

**Part C Qualified Independent
Contractor (QIC)**

**PACE Organization
Reconsideration Procedures Manual**

C2C Innovative Solutions, Inc.

Effective May 1, 2026

Part C QIC C2C Innovative Solutions, Inc. (C2C) Contact Information

Part C QIC Website: <https://partcappeals.c2cinc.com/>

Part C QIC Secure Appeals Portal Accessible At: <https://partcappeals.c2cinc.com/>

Part C QIC Plan Liaison Contact Information	
Email: PartC-Plan_Liaison@c2cinc.com	Telephone: 1-866-439-0863

Part C QIC Appeals Portal Usage Alert for All PACE Organizations:

C2C is working diligently to continue enhancements to the Part C QIC Appeals Portal. With the May 1, 2026 launch, PACE Organizations will have limited initial functionality within the Portal and will not yet be able to submit cases or complete other case-specific communications with the QIC through the Portal. The tables below outline the Day 1 capabilities for interacting with the QIC.

C2C is actively enhancing the portal environment to develop a PACE-specific reconsideration form, which will allow PACE Organizations to submit reconsideration cases and case files directly to the Part C QIC through the Portal in the near future. Once available, we will notify all registered portal users, update the PACE Organization Reconsideration Procedures Manual, and communicate through additional channels to ensure PACE Organizations are aware that Portal submission functionality is ready for use.

Expedited Reconsideration Appeal Requests	
UPS / FedEx Only C2C Innovative Solutions, Inc. - QIC Part C Attn: QIC Part C - Expedited 301 W. Bay St., Suite 1110 Jacksonville, FL 32202	
Telephone for PACE Organizations	1-866-439-0863
Telephone for Enrollees	1-866-320-0963
Telephone for Providers	1-866-320-0963

Fax Number for PACE Organization, Provider/Supplier, or Enrollee Submission of Additional Documentation in Response to IRE Request for Information (RFI) related to a pending Expedited Appeal	904-539-4075
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All Other Reconsideration Appeal Requests	
<p style="text-align: center;">Alternative Method*: United States Postal Service (USPS)</p> <p style="text-align: center;">C2C Innovative Solutions, Inc. - QIC Part C Attn: QIC Part C – New Appeals P.O. Box 1949 Jacksonville, FL 32231-0053</p>	<p style="text-align: center;">Alternative Method: UPS / FedEx Only</p> <p style="text-align: center;">C2C Innovative Solutions, Inc. - QIC Part C Attn: QIC Part C – New Appeals 301 W. Bay St., Suite 1110 Jacksonville, FL 32202</p>
<p style="text-align: center;">USPS Address for All Other Correspondence Not Related to a New Appeal Request:</p> <p style="text-align: center;">C2C Innovative Solutions, Inc. - QIC Part C Attn: QIC Part C – Correspondence P.O. Box 1949 Jacksonville, FL 32231-0053</p>	<p style="text-align: center;">UPS / FedEx Only Address for All Other Correspondence Not Related to a New Appeal Request:</p> <p style="text-align: center;">C2C Innovative Solutions, Inc. - QIC Part C Attn: QIC Part C – Correspondence 301 W. Bay St., Suite 1110 Jacksonville, FL 32202</p>
<p style="text-align: center;">Telephone for PACE Organizations</p>	1-866-439-0863
<p style="text-align: center;">Telephone for Enrollees</p>	1-866-320-0963
<p style="text-align: center;">Telephone for Providers</p>	1-866-320-0963
Fax for PACE Organization, Provider/Supplier or Enrollee Submission of Additional Documentation in Response to IRE RFI on a Part B Drug Appeal	904-539-4076
Fax for PACE Organization, Provider/Supplier, or Enrollee Submission of Additional Documentation in Response to IRE RFI on Any Other Appeal Type	904-539-4078

***USPS method of submission is not applicable for Standard Part B Drug appeals given the compressed timeframes. These appeals should be sent to the IRE via UPS/FedEx Only.**

Options for PACE Organizations to Submit Statements of Effectuation Compliance to IRE	
Fax Number for Plans to Submit Statement of Compliance Form	904-539-4096
<p align="center">United States Postal Service (USPS)</p> <p align="center">C2C Innovative Solutions, Inc. - QIC Part C Attn: QIC Part C – Effectuation Compliance P.O. Box 1949 Jacksonville, FL 32231-0053</p>	<p align="center">UPS / FedEx Only</p> <p align="center">C2C Innovative Solutions, Inc. - QIC Part C Attn: QIC Part C – Effectuation Compliance 301 W. Bay St., Suite 1110 Jacksonville, FL 32202</p>

PACE Organization Requests for IRE Reopening	
<p align="center">United States Postal Service (USPS)</p> <p align="center">C2C Innovative Solutions, Inc. - QIC Part C Attn: QIC Part C – Reopening P.O. Box 1949 Jacksonville, FL 32231-0053</p>	<p align="center">UPS / FedEx Only</p> <p align="center">C2C Innovative Solutions, Inc. - QIC Part C Attn: QIC Part C - Reopening 301 W. Bay St., Suite 1110 Jacksonville, FL 32202</p>

PACE Organization Submission of Additional Information Authorizing Coverage or Payment for an Item, Service, or Part B Drug Subsequent to the PACE Organization Submission of the Case and Case File to the IRE for Processing of the IRE Reconsideration	
<p>Fax Number for PACE Organization to Submit Additional Information Indicating PACE Organization Authorization of Coverage or Payment for an Item, Service or Part B Drug Subsequent to the Submission of the Case and Case File to the IRE for Processing of the IRE Reconsideration. Please use the Fax Number as Denoted by the Appeal Type.</p>	<p align="center">Expedited Appeal: 904-539-4075 Standard Part B Drug: 904-539-4076 Any Other Appeal Type: 904-539-4078</p>

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1. INTRODUCTION

Section 1894(f) of the Social Security Act directs CMS to establish external appeals rights under Medicare for Program of All-Inclusive Care for the Elderly (PACE). 42 Code of Federal Regulations (CFR) §460.124 establishes that Medicare PACE participants, referred to as enrollees in this manual, have the right to a reconsideration by an Independent Review Entity (IRE). The Centers for Medicare & Medicaid Services (CMS) has contracted with C2C Innovative Solutions, Inc. (C2C) to serve as the IRE, also referred to as the Part C Qualified Independent Contractor (Part C QIC).

This Manual contains the guidelines and procedures for the coordination between PACE Organizations and C2C in the processing of reconsiderations and related reconsideration activities for PACE enrollees. The IRE reconsideration step is part of a multi-level Medicare appeal process. This manual is not intended to serve as a review of CMS policy governing PACE Organization obligations under the Medicare appeal process. It presumes that the reader has a command of the relevant Part C Medicare rules and policies as set forth in:

- 42 CFR Part 460, Subpart G
- CMS IOM Pub. 100-11, Chapter 11
- CMS Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance
- CMS Program Memoranda and Transmittals
- HPMS issuances

Insofar as concerns operational policies and procedures relevant to working with the IRE, some of the policies and procedures addressed in this Manual are mandatory and complete compliance by the PACE Organization is required. For such requirements, the term "must" or "mandatory" is used. Some policies and procedures provide the Medicare Health Plan with flexibility but offer suggestions for working with the IRE that may result in more efficient and seamless appeals processing for plans, enrollees and other stakeholders. In these areas, the term "recommended," "suggested" or "optional" is used.

2. DEFINITIONS

The following definitions are provided only for use in this Manual. These definitions do not encompass all terms referenced in 42 CFR Parts 422 or 460 and, in some cases, paraphrase or summarize regulatory text. In the event of any discrepancies or inconsistencies, the governing regulations at Parts 422 or 460 prevail.

2.1 ADJUDICATOR

An appeal professional employed by C2C to manage reconsideration case files. Adjudicators make coverage determinations. Adjudicators do not make medical necessity determinations. Medical necessity determinations are made by C2C's fully credentialed board- certified physicians.

2.2 APPEAL

A review of a PACE organization's denial or partial denial of a service determination request that is contested by the enrollee or an authorized representative. The term appeal refers to this review process under the PACE organization's internal appeal procedures and, when applicable, the external Medicare reconsideration conducted by the IRE or the State Fair Hearing processes.

2.3 APPEAL PROCESS

The appeal process is the multi-level Medicare review framework through which an enrollee may challenge a denial or partial denial of a PACE Organization service determination request, or an adverse action under Medicare managed care rules. For PACE, the IRE (Part C QIC) conducts the Medicare reconsideration level of review in accordance with 42 CFR Part 422, Subpart M, which governs the IRE reconsideration process. This reconsideration serves as the external Medicare appeal level available to PACE enrollees under 42 CFR § 460.124.

2.4 AUTHORIZED REPRESENTATIVE

An individual appointed by an enrollee to represent him/her in filing an appeal.

2.5 DE NOVO REVIEW

A review of by a new and impartial reviewer. The new and impartial reviewer does not give preference to any previous determinations made.

2.6 ENROLLEE

A Medicare beneficiary who is enrolled in a Program of All-Inclusive Care for the Elderly (PACE). Under 42 CFR § 460.6, such an individual is referred to as a *participant* in the PACE program. For purposes of this Manual—which applies only to Medicare participants enrolled in a PACE Organization—the terms **enrollee** and **participant** are used interchangeably.

2.7 PACE PARTICIPANT RIGHTS AND COVERAGE INFORMATION

The written materials a PACE Organization must provide to participants enrolled in PACE. Under 42 CFR Part 460, this includes the Enrollment Agreement and the PACE Participant Bill of Rights, which together describe the participant's rights, responsibilities, available services, and conditions of participation in the PACE program. Together, these materials function as the PACE program's operational equivalent of an Evidence of Coverage used in Medicare managed care.

2.8 EXPEDITED RECONSIDERATION

An expedited reconsideration is a de novo review of a PACE Organization's denial, reduction, or termination of a service when the participant or the participant's representative believes that waiting for a standard reconsideration would place the participant's life, health, or ability to regain or maintain maximum function at serious risk, consistent with 42 CFR § 460.122(f).

For PACE appeals, the IRE must process an expedited reconsideration as expeditiously as the participant's health condition requires, but no later than 72 hours after receipt. The IRE may extend this timeframe by up to 14 calendar days for appeals related to

items and services, if the IRE determines that an extension is necessary to obtain additional information and the delay is in the participant's best interest.

The IRE also has authority to determine whether a request meets the criteria for expedited processing. Accordingly, C2C may convert an expedited request to a standard reconsideration if the criteria are not met or may elevate a standard request to expedited when the participant's medical condition requires faster action.

2.9 INDEPENDENT REVIEW ENTITY (IRE)

The entity under contract with CMS to perform reconsideration of denials upheld at the lower appeal level. C2C is the Independent Review Entity. C2C may also be referred to as the Part C QIC.

2.10 LOCAL COVERAGE DECISION (LCD)

A policy document that is published by a Medicare fee-for-service (FFS) contractor with jurisdiction over fee-for-service claims in a defined area that specifies coverage or clinical criteria for claim reimbursement.

2.11 MEDICARE ADVANTAGE ORGANIZATION

An entity that is under contract with CMS to provide Medicare benefits to Medicare beneficiaries. Medicare Advantage Organizations offer Medicare Advantage Plans such as HMOs, PSOs, PPOs, SNPs MSAs, private FFS plans and other programs and projects. The determination of whether an entity is subject to the Medicare Advantage appeal requirements is made by CMS.

2.12 MEDICARE APPEAL SYSTEM (MAS)

The CMS system of record that C2C uses to populate specific data elements from reconsideration cases and to generate required reports for CMS.

2.13 MEDICARE HEALTH PLAN

A term used in the Medicare Health Plan Manual and in C2C correspondence to refer to a Medicare Advantage Plan, Cost Plan, Dual Eligible Plans, and/or HCPP.

2.14 PACE DETERMINATION

A PACE service determination is the PACE organization's initial decision to approve, modify, continue, or deny a participant's request for a service. This includes requests to initiate a new service, increase or decrease an existing service, or continue a service that the PACE organization proposes to reduce or discontinue. The decision reflects whether the requested service is necessary to meet the participant's medical, physical, emotional, or social needs, in accordance with the PACE benefit package and the requirements of 42 CFR § 460.92 and § 460.121. The PACE organization must have procedures for making both standard and expedited service determinations. An expedited review is required when applying standard timeframes could seriously jeopardize the participant's life, health, or ability to regain or maintain maximum function, as outlined in 42 CFR § 460.121 and § 460.122(f). A denial or partial denial of a service determination constitutes an action that gives the participant the right to file an appeal, which must be processed in accordance with the PACE organization's appeals process under 42 CFR § 460.122.

2.15 RECONSIDERATION (i.e., IRE External Review)

An external review is the level of appeal available to a participant after the PACE organization issues an adverse appeal decision. Under 42 CFR § 460.124, Medicare-eligible participants may request review by the Medicare Independent Review Entity (IRE), and Medicaid-eligible participants may request a State Fair Hearing. Participants who are eligible for both Medicare and Medicaid may choose either the IRE or the State Fair Hearing process but may pursue only one route for a given appeal. The IRE conducts the Medicare external review and issues its decision in the form of a reconsideration, which is the term used by the IRE for its determination at this level of review.

2.16 RECONSIDERATION DETERMINATION NOTICE

The letter used by the IRE to communicate the final decision in a reconsideration.

2.17 REOPENING

A review of a completed IRE reconsideration determination undertaken at the sole discretion of the IRE for the purpose of addressing new information received or a potential error in the determination (See 42 CFR §422.616).

2.18 REQUEST FOR INFORMATION (RFI)

A document submitted by the IRE to the PACE Organization, enrollee (or their representative), or a provider, requesting additional information for adjudication. The IRE may issue a request for information and extend the adjudication timeframe in expedited and standard pre-item or service cases by up to 14 calendar days if requested by the enrollee or needed to address deficiencies in the case file (with notice to the enrollee).

2.19 STANDARD PAYMENT (CLAIM) RECONSIDERATION

Reconsiderations related to a denial of claim payment or reimbursement. Standard payment (claim) reconsiderations must be completed by the IRE within 60 days of request receipt, may not be expedited, and are not subject to any extensions. A standard payment reconsideration may also be referred to as a retrospective appeal.

2.20 STANDARD ITEM or SERVICE RECONSIDERATION

Reconsiderations of denials of authorization for items or services, including continuing services, that do not meet the criteria for an expedited reconsideration. Standard item or service reconsiderations must be completed by the IRE within 30 calendar days of the request receipt, subject to a possible 14-calendar day extension if a request for information is issued.

2.21 STANDARD PART B DRUG RECONSIDERATION

Reconsideration of denials of authorization for Medicare Part B coverable drugs, including continuation of usage of a Part B drug, which do not meet criteria for an expedited reconsideration. Standard Part B drug reconsiderations must be completed by the IRE within 7 calendar days of the request's receipt. These requests are not subject to any extensions.

3. WORKING WITH C2C

This section explains the processes for communicating with C2C, including:

- 3.1 Sources of Information about IRE Reconsiderations
- 3.2 Set-up of New PACE Organizations
- 3.3 Identifying and Changing PACE Points of Contact
- 3.4 Seeking Information about Current/Active Cases
- 3.5 Suggestions and Complaints
- 3.6 Holidays

Note: C2C is not authorized to guide or instruct PACE Organizations on interpretation of CMS coverage policies or matters related to PACE Organization compliance with CMS' appeals process requirements.

3.1 SOURCES OF INFORMATION ABOUT IRE RECONSIDERATIONS

- *C2C PACE Organization Reconsideration Procedures Manual:* C2C makes this Manual available to Organizations to provide information about IRE appeals processing. This Manual is available on the C2C website and is applicable for PACE Organizations. C2C also provides a Manual for Medicare Health Plans that is available on the C2C website. Health Plans and PACE Organizations may download these Manuals from C2C's website.
- *C2C website:* The C2C Part C QIC website (<https://partcappeals.c2cinc.com/>) contains information such as:
 - Links to CMS websites of the statutes, regulations and policies
 - C2C contact information
 - Effectuation Information for Part C QIC Reconsiderations
 - Appeal Status Information for Part C QIC Appeals
 - **Note:** Case status information on the website is limited to protect enrollee and Medicare Health Plan confidentiality. A case can only be accessed by the reconsideration case number that is assigned by the Medicare Appeal System when a case file is received from a Health Plan. A reconsideration case number has no logical ties to a Social Security Number, Medicare Number, or any other confidential information. The information that can be obtained by entering the reconsideration case number is limited to the following:
 - IRE Case Number (i.e., the MAS Appeal Number)
 - IRE Request Received Date
 - IRE Appeal Priority
 - Plan Reported Reconsideration Receipt Date (from the Medicare Managed Care Reconsideration Background Data Form)
 - IRE Corrected Recon Receipt Date (if different than the Plan Reported Recon Receipt Date)
 - Plan Timeliness of Appeal Processing
 - Plan Extension (Y/N)
 - IRE Reconsideration Deadline

- IRE Reconsideration Decision
 - IRE Reopen Decision (if applicable)
 - ALJ Decision (if applicable)
 - Last Decision Date
 - Plan Organization
 - Reconsideration Data from this website can be exported into either an Excel or .csv format
- *Part C QIC Newsletter*: When directed by CMS, C2C publishes a newsletter. This newsletter addresses commonly observed situations in the IDR reconsideration process and provides updates to C2C’s policies and procedures. Newsletters that are published will be available to Health Plans and PACE Organizations through C2C’s website.

3.2 SET-UP OF PACE ORGANIZATIONS WITH C2C

An entity that has established a new PACE Organization contract with CMS should contact C2C prior to its first enrollment effective date. C2C provides an online contact form for Organizations to provide C2C with key contact information. This form is available via the PACE Reconsideration Procedures Manual Appendix available on the Part C QIC website at <https://partcappeals.c2cinc.com/>.

3.3 IDENTIFYING AND CHANGING PACE ORGANIZATION POINT OF CONTACT

PACE ORGANIZATION KEY ORGANIZATION CONTACT: Each Organization must designate and maintain one or two key organizational contacts. Organizations operating under multiple CMS contract numbers must designate a key contact person for each contract; however, the same individual(s) may serve as the contact for multiple contracts if appropriate. These individuals serve as the primary point of contact for C2C and will receive important communications, as well as outreach if an issue arises with a specific case.

As part of the IRE transition, Organizations were required to provide C2C with their key organization contact information through the online form on the C2C Part C QIC website. Organizations that did not submit the required information prior to the May 1, 2026, cutover—or Organizations that wish to update their information after the cutover—may continue to access this online form to provide new organization contacts or to review and update their organization specific key organization contact information as needed. In lieu of completing online, please download the form from the Appendix and return to the Plan Liaison: PartC-Plan_Liaison@c2cinc.com.

PACE ORGANIZATION INDIVIDUAL RECONSIDERATION CASE CONTACTS:

An organization must also list a case specific contact person when submitting a reconsideration case request on the *Medicare Managed Care Reconsiderations Background Data Form*. An organization may, but is not required to, use its key contact as the designated case specific contact. An organization may vary the case specific contact person from case to case. Note: IRE decision notices, and as applicable, the Notice to Comply with a respective IRE decision, will be faxed from the IRE to the

number provided in the case specific contact section of the Reconsiderations Background Data Form.

3.4 SEEKING INFORMATION ABOUT SPECIFIC CASES

An organization can obtain basic information concerning the status of active and decided cases via C2C's Part C QIC website: <https://partcappeals.c2cinc.com/>. In addition, you may call us at 1-866-439-0863.

For inquiries about the processing status of a specific case file, or group of cases, please visit our Part C QIC website: <https://partcappeals.c2cinc.com/>.

Specific inquiries from an organization regarding a case under review may be directed to the Plan Liaison at PartC-Plan_Liaison@c2cinc.com. Any information intended for inclusion in the case file, or that may be used as documentation for the final determination, must be submitted in writing through the appropriate submission process. **Such information must not be sent to this email inbox. Note: Organizations must not transmit protected health information (PHI) to this email address.**

Organizations are responsible for supporting their enrollees in the reconsideration process. Organizations should not direct members to C2C for routine case status inquiries.

Medicare enrollees should be referred to 1-800-MEDICARE for general information regarding the appeals process and to locate resources for assistance.

3.5 SUGGESTIONS AND COMPLAINTS

Please provide any suggestions or complaints to any C2C staff member who is interacting with you or to the Plan Liaison via email at PartC-Plan_Liaison@c2cinc.com or via telephone at 1-866-439-0863.

3.6 HOLIDAYS

C2C's offices are closed in observance of the following Federal and Corporate holidays:

- New Year's Day
- Memorial Day
- Independence Day
- Labor Day
- Thanksgiving Day
- Friday following Thanksgiving
- Christmas Eve
- Christmas Day

If a holiday falls on a Saturday, it is observed the preceding Friday; if it falls on a Sunday, it is observed the following Monday.

4. BACKGROUND - IMPORTANT CONSIDERATIONS PRIOR TO DEVELOPING THE RECONSIDERATION CASE FILE FOR SUBMISSION

This Chapter highlights certain aspects of PACE Organization service determination, internal appeal responsibilities, and actions that support the ensuing external appeals process afforded to participants. The topics addressed are:

- 4.1 PACE Organization Service Determination Responsibilities
- 4.2 PACE Organization Internal Appeals Process
- 4.3 PACE Organization External Appeal Responsibilities

4.1 PACE ORGANIZATION SERVICE DETERMINATION RESPONSIBILITIES

Under 42 CFR § 460.121, the PACE organization is responsible for receiving, documenting, and processing all service determination requests made by a participant, their representative, or caregiver. The organization must bring each request to the Interdisciplinary Team (IDT) as quickly as the participant's condition requires, but no later than three calendar days after the request. The IDT must consider all relevant information—including assessment findings and criteria under § 460.92—to decide whether to approve, modify, continue, or deny the requested service. If the IDT expects to deny or partially deny the request, appropriate team members must conduct an in-person reassessment before issuing the decision.

The PACE organization must notify the participant or representative of the determination as expeditiously as the participant's condition requires, but no later than three calendar days after receiving the request, unless a permissible extension applies. Extensions of up to five (5) additional calendar days may be used only when (1) the participant or representative requests the extension, or (2) the IDT needs additional information from an external party, and the delay is in the participant's best interest. The organization must issue notice of the extension within 24 hours and explain the reason for the delay.

When communicating a decision, the PACE organization must explain the outcome (approval, modification, or denial); the expected timeframe for any approved services; and, for denials or partial denials, must provide both oral and written notice stating the specific reason for the decision, how the service is not necessary to maintain or improve the participant's overall health status, and the participant's appeal rights under §460.122. If the approved service is granted, the organization must furnish it as expeditiously as the participant's condition requires.

4.2 PACE ORGANIZATION INTERNAL APPEALS PROCESS

Under 42 CFR § 460.122, the PACE Organization must maintain a formal, written internal appeals process to address any adverse service determination, including non-coverage, non-payment, reductions, or terminations of services. An internal appeal is initiated when a participant or their authorized representative disagrees with the PACE Organization's determination and requests further review. In accordance with CMS Internet Only Manual (IOM) Publication 100-11, Chapter 11, Section 20, the PACE Organization must make appeal procedures available to all participants at enrollment, annually thereafter, and whenever a service determination is denied.

Upon receiving an appeal request, the PACE Organization must promptly document the appeal and ensure that all required information is included in the participant's appeal record, consistent with § 460.122(c). The appeal must be reviewed by an appropriately

credentialed and impartial third-party reviewer or committee—that is, an individual who was not involved in the original decision and who does not have a stake in the outcome.

The PACE Organization is responsible for resolving appeals as expeditiously as the participant's health condition requires, but no later than 30 calendar days after receipt of the appeal. For cases requiring more immediate action, the PACE Organization must provide an expedited appeal process, completing its review within 72 hours, unless an extension of up to 14 days is warranted at the participant's request or in the participant's best interest, consistent with § 460.122(f) and IOM 100-11, Chapter 11, Section 20.3.

Throughout the appeal, the PACE Organization must ensure that the participant continues to receive all required services. For Medicaid participants, if the appeal involves a proposed termination or reduction of ongoing services, the PACE Organization must continue furnishing the disputed services upon request until a final determination is made, as required under § 460.122(e).

When issuing a decision, the PACE Organization must provide the participant or representative with a written notice that includes: (1) the decision outcome (favorable, partially favorable, or adverse); (2) the specific reasons for any denial; (3) an explanation of how the decision was reached; and (4) information about the participant's right to pursue external review through either the Independent Review Entity (IRE) or State Fair Hearing, as outlined in § 460.124 and PACE IOM Chapter 11, Section 20.4.

4.3 PACE ORGANIZATION EXTERNAL APPEAL RESPONSIBILITIES

Under 42 CFR § 460.124, the PACE organization must inform every participant, in writing, of their right to seek external review after the PACE internal appeals process is complete. PACE Organizations must also assist participants in understanding and exercising these rights by explaining the applicable external appeal route(s) based on the participant's Medicare and Medicaid status. For Medicare beneficiaries, PACE must advise that they may request reconsideration through the Medicare Independent Review Entity (IRE); for Medicaid-eligible individuals, PACE must explain the right to a State Fair Hearing. Participants who are dually eligible for both Medicare and Medicaid must be informed that they may choose only one of these external processes for a given appeal.

Under 42 CFR § 460.124, when a participant elects an external appeal option, the PACE organization is responsible for forwarding the appeal to the correct external entity in a timely manner and providing all required documentation. Additionally, PACE must continue furnishing all required services—including disputed services for Medicaid participants when continuation criteria are met—while the external appeal is pending, consistent with the statutory requirement that PACE participants receive all benefits solely through the PACE organization.

These responsibilities ensure that participants have access to an independent, impartial review of adverse determinations and that PACE organizations support participants throughout the full appeals process.

4.4 PACE ORGANIZATION RESPONSIBILITY TO CONDUCT A FULL INTERNAL APPEAL

Under 42 CFR § 460.122 and the CMS PACE Manual (IOM 100-16, Chapter 11), the PACE Organization is responsible for conducting a comprehensive internal appeal whenever a participant contests an adverse service determination. The internal appeal must be reviewed by an appropriately credentialed, impartial third-party reviewer or review committee who was not involved in the original decision and has no stake in the outcome. As part of the internal appeal, the PACE Organization must thoroughly evaluate all relevant clinical information, the basis for the service determination, any required reassessment findings, and all materials submitted by the participant or representative. The PACE Organization must complete the internal appeal as expeditiously as the participant's health condition requires, and no later than 30 days for standard appeals or 72 hours for expedited appeals, consistent with regulation and the IOM. During the internal appeal, the PACE Organization must continue providing all required services, including disputed services for Medicaid participants when continuation criteria are met.

C2C may, at its discretion, utilize the "Request for Additional Information" (RFI) process (See Section 6.6) to direct the PACE Organization to remedy a case file in which the complete internal appeal process has not been documented or where the case file is missing documentation.

C2C will notify CMS if a PACE Organization displays a pattern of failure to complete and document a thorough internal appeal.

5. SUBMITTING RECONSIDERATION CASE FILES TO C2C

This Chapter defines the requirements for PACE Organization preparation and submission of case files to C2C for IRE reconsideration under the following headings:

- 5.1 Submission of External Appeal Cases to C2C
- 5.2 C2C Business Hours and QIC Appeals Portal Availability
- 5.3 Preparation and Submission of the New Case File to C2C

5.1 SUBMISSION OF EXTERNAL APPEAL CASES TO C2C

Under 42 CFR § 460.124, a PACE participant or their representative has 60 calendar days from the date of the adverse determination to request an external appeal. Depending on the participant's Medicare and/or Medicaid eligibility, this external appeal may be through the Medicare Independent Review Entity (IRE) or the State Medicaid Fair Hearing process. Upon receiving such a request, the PACE organization must promptly forward the appeal and all relevant documentation to the appropriate external entity. The PACE organization is responsible for assisting participants in understanding their external appeal rights, ensuring the request is filed within the 60-day timeframe, and transmitting the complete case file to the external review entity without unnecessary delay. The PACE organization should maintain records of all forwarded appeals and cooperate fully with the external review entity throughout the process

5.2 C2C BUSINESS HOURS AND QIC APPEALS PORTAL AVAILABILITY

Telephone Contact: The IRE will respond to telephone inquiries and return calls during customer service business hours, Monday through Friday from 8:00 AM to 7:00 PM

EST. Messages received outside of these hours will be returned by the customer service team within 24 business hours.

Case and Case File Submission from Plan to QIC: Upon future implementation of PACE Organization functionality in the QIC Appeals Portal, PACE organizations are strongly encouraged to submit participant external appeals and case files through the portal. C2C will notify PACE organizations when this functionality becomes available. Once available, the QIC Appeals Portal will be open 24 hours a day, seven days a week¹. The portal submission date will be used as the receipt date of the case file for purposes of calculating PACE Organization timeliness.

Exhibit 5-1: EXPEDITED CASE HARD COPY SUBMISSION TIMETABLE:

<i>Day of the Week of the Medicare PACE Organization Internal Appeal Determination</i>	<i>Day of the Week of the PACE Organization Case Submission to Overnight Delivery Vendor</i>	<i>Day of the Week of C2C's Receipt</i>
Monday	Tuesday	Wednesday
Tuesday	Wednesday	Thursday
Wednesday	Thursday	Friday
Thursday	Friday	Saturday*
Friday	Saturday*	Monday
Saturday	Monday	Tuesday

*Some delivery vendors require senders to specify "Saturday Delivery" on the envelope/package to be delivered. C2C is open to receive cases on Saturday and Sunday from 10:00 am to 3:00 PM EST.

5.3 PREPARATION AND SUBMISSION OF THE NEW CASE FILE TO C2C

Addressed below are instructions for the PACE organization on the required methods for physical construction of a case file submitted to C2C for IRE reconsideration. The topics are addressed under the following subheadings:

- 5.3.1 Initiation of Expedited Cases
- 5.3.2 Organization of the New Case File Package
- 5.3.3 Organization of Individual New Case Files
- 5.3.4 Guidance on Selection and Inclusion of Medical Records
- 5.3.5 Confirmation of C2C Case Receipt

As explained below, the PACE Organization must include with each case a *PACE Reconsideration Background Data Form* and a structured Case Narrative report. The instructions for this form and report are presented in Appendix and should be thoroughly reviewed since the instructions are integral to an understanding of case preparation and submission requirements.

Please note: Upon implementation of PACE Organization functionality for new case submission in the QIC Appeals Portal, the data entry required for submission of a case file through QIC Appeals Portal will be equivalent to the *PACE Reconsideration*

¹ With the exception of routine scheduled maintenance or emergency maintenance to fix user issues, the portal will be available.

Background Data Form; no separate form needs to be submitted for case files sent via the QIC Appeals Portal. For all cases, including those submitted via the QIC Appeals Portal, a structured Case Narrative report is required.

5.3.1 INITIATION OF EXPEDITED CASES

When functionality is available, PACE organizations are encouraged to submit expedited case files and the ensuing documentation through the QIC Appeals Portal. PACE organizations must not fax or email case files to C2C. C2C will not initiate any case that is sent via facsimile until a hard copy or portal-submitted copy of the case file is received. Follow the instructions for case delivery in Section 5.3.2.

5.3.2 ORGANIZATION OF THE NEW CASE FILE PACKAGE

The "New Case File Package" is the envelope or container in which the PACE Organization ships C2C one or more new case files. C2C offices are open to accept case file delivery Monday through Saturday. Address packages using the appropriate address listed in the Contact Information section at the beginning of this Manual.

When submitting paper case files, the PACE Organization may include more than one new case in a package submitted to C2C, but it is imperative to clearly separate individual case files from one another to prevent issues with intermingling enrollee information.

Upon implementation of PACE Organization functionality for new case submission in the QIC Appeals Portal, C2C will accept delivery of case files through the QIC Appeals Portal 24 hours a day/7 day a week². The receipt date for purposes of PACE Organization submission timeliness is the actual date/time of portal submission.

When submitting electronic case files using the QIC Appeals Portal, the Organization may include only one new case in each package submitted to C2C.

For all hard copy case file submissions submitted to C2C via mail or overnight delivery:

- Complete and place the New Reconsideration Case File Transmittal Cover Sheet form (See Appendix) on top of the case file package.
- Bind each case in the package separately; using clips or other methods that can be removed without special equipment is permissible.
- Do not staple or permanently bind case file material.

5.3.3 ORGANIZATION OF INDIVIDUAL NEW CASE FILES

The organization of the case should be in the following order, "top" of file to "bottom."

- *PACE Reconsideration Background Data Form* (See Appendix)
- Case Narrative (See Appendix)
- Case Material

EXPLANATION OF "CASE MATERIAL":

² With the exception of routine scheduled maintenance or emergency maintenance to fix user issues, the portal will be available.

"Case material" refers to all supporting notices, documentation, medical records, call logs, and so forth. Some examples of case materials to include are noted below. Case material should be placed in a standard order, "top" of file to "bottom," as shown below.

- Notices:
 - Representative Documentation (if applicable)
 - Service Determination Notice to the Participant (or representative)
 - Notice of Extension of Service Determination Decision (if applicable)
 - Notice of Extension of Internal Appeal Decision (if applicable)
 - Notice of Internal Appeal Decision and External Appeal Rights

- Record of Adverse Determination and PACE Reconsideration
 - Prior authorization or service denial notices
 - Medical Director or IDT consultant determinations
 - Any clinical assessments, care plans, or relevant participant evaluations
 - Written or verbal statements from the participant, their representative, or provider
 - Provider letters of support or consultations
 - Any relevant call logs or system reports
 - Relevant correspondence and reports related to the determination or appeal
 - Any other records maintained by the PACE organization regarding the determination or internal appeal process

- PACE Organization Decision Making Criteria
 - Complete copy of the participant's enrollment agreement or other documentation establishing eligibility and scope of covered services (preferably in electronic format, e.g., on CD-ROM or USB drive)
 - Full citation for any CMS policy references, or copy of text*
 - Complete copy of any referenced internal medical policy, utilization review criteria, technology assessment, or other cited medical criteria
 - Any additional documentation or references relied upon by the IDT or Medical Director in making the determination.

- Medical Records (See Section 5.3.4)

* *Note:* "Full citation" refers to the designation of section and paragraph of the Social Security Act or CFR, and the referenced CMS IOM Manual - Chapter/Section. A copy is not required for these citations. For Local Coverage Decisions, a copy must be included unless an active and complete citation is provided via a web address. Do not cite secondary sources (for example, MCG/Milliman, InterQual, or proprietary internal policies) unless complete text is provided.

5.3.4 GUIDANCE ON SELECTION AND INCLUSION OF MEDICAL RECORDS

For denials that are based, in whole or part, on medical necessity, the PACE Organization must provide a "peer defensible" rationale for the denial. Medical records

that relate to the case issues must be included. Medical records that do not relate to the case should not be included.

If the PACE organization has made one or more unsuccessful attempts to obtain records, such attempts should be documented. For example, the Organization may include a statement within the Case Narrative (Section IV (B) Justification) detailing the attempts made to obtain the records and the basis of why it arrived at its decision without these records.

Medicare allows PACE Organizations to use step therapy for Medicare Part B drugs to manage its formulary. This is the process of beginning drug therapy for a medical condition with "preferred" (or more cost-effective) on-formulary drug alternative(s) and progressing to other drug therapies only as necessary. An organization must grant an exception to its step therapy coverage rules for Medicare Part B drugs if it determines that the requested drug is medically necessary, consistent with the prescriber's statement and the medical records. The physician statement and the medical records must show that the step therapy drugs:

1. Have been ineffective in treating the enrollee; or
2. Are likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or
3. Are likely to cause an adverse reaction or other harm to the enrollee.

The documentation required in the case file from the organization is as follows:

- Organization specific Step Therapy edits and rules for the Part B drug
- Enrollee physician statement regarding trial and failure of specific medications
- Enrollee medical records regarding previous treatments
- Entire Evidence of Coverage /Plan Formulary and any addendums regarding Medicare Part B drugs.

Exhibit 5-3: Suggested Medical Records for Inpatient and Long-term Care Denials and Exhibit 5-4: Suggested Medical Records for other Common Types of Denials are offered by C2C to reduce the need for requests for additional information to the PACE Organization. The Organization should regard these examples as a general guide. Requirements for a given case may vary. C2C reserves the right to request records in addition to those listed in these examples should the situation warrant the request.

Exhibit 5-3: SUGGESTED MEDICAL RECORDS FOR INPATIENT AND LONG-TERM CARE DENIAL

Medical Records	Acute Hospital Admission Denial	Acute Hospital Continued Care Denial	SNF Admission Denial	SNF Continued Care Denial	Inpatient Rehabilitation Admission Denial	Inpatient Rehabilitation Denial
PCP Records	X					
Specialist Records	X					
Treating Physician Support for Denial	X	X	X	X	X	X

Medical Records	Acute Hospital Admission Denial	Acute Hospital Continued Care Denial	SNF Admission Denial	SNF Continued Care Denial	Inpatient Rehabilitation Admission Denial	Inpatient Rehabilitation Denial
Alternate Care Recommendations	X	X	X	X	X	X
Pre-Admission Screening					X	X
Admission Orders*		X	X (hospital)	X (SNF)	X (hospital or SNF)	X (rehab)
Doctor's Orders*		X	X (hospital)	X (SNF)	X (hospital or SNF)	X (rehab)
Admission History and Physical*		X	X (hospital)	X	X (hospital or SNF)	X (rehab)
Discharge Note*		X	X (hospital)	X (hospital)	X (hospital or SNF)	X (hospital, SNF, rehab)
Physician Progress Notes*		X	X (hospital)	X (hospital and SNF)	X (hospital or SNF)	X (rehab)
Nurses Notes*		X	X (hospital)	X (SNF)	X (hospital or SNF)	X (rehab)
Nursing Care Plan*		X		X (SNF)	X (hospital or SNF)	X (rehab)
Medication Record*		X	X (hospital)	X (SNF)	X (hospital or SNF)	X (rehab)
Treatment Records (e.g., wound care)*		X	X (hospital)	X (SNF)	X (hospital or SNF)	X (rehab)
Diagnostic Studies*		X	X (hospital)	X (SNF)	X (hospital or SNF)	X (rehab)
Laboratory Studies*		X	X (hospital)	X (SNF)	X (hospital or SNF)	X (rehab)
Physical Therapy Admission and Discharge Notes*				X (SNF)	X (hospital or SNF)	X (rehab)
Physical Therapy Progress Records*		X	X (hospital)	X (hospital and SNF)	X (hospital or SNF)	X (rehab)
Occupational Therapy Admission and Discharge Notes*				X (SNF)	X (hospital or SNF)	X (rehab)
Occupational Therapy Progress Records*		X	X (hospital)	X (hospital & SNF)	X (hospital or SNF)	X (rehab)
Speech Therapy Admission and Discharge Notes*				X (SNF)	X (hospital or SNF)	X (rehab)
Speech Therapy Progress Notes*		X	X (hospital)	X (hospital and SNF)	X (hospital or SNF)	X (rehab)
Nutrition Therapy Notes*		X	X (hospital)	X (SNF)	X (hospital or SNF)	X (rehab)
Discharge Planning Notes*		X	X (hospital)	X (SNF)	X (hospital or SNF)	X (rehab)
Records on prior level of functioning			X	X	X	X

*Records may be from an acute care hospital, a SNF, or an inpatient rehabilitation facility depending on the ease types and basis for denial.

Exhibit 5-4: SUGGESTED MEDICAL RECORDS FOR OTHER COMMON TYPES OF DENIALS

Issue at Appeal	Records Needed
Mobility Aids (PMDs, power wheelchairs, manual wheelchairs, walkers, canes)	PCP records, Physical Therapy records, Orthopedic records, Neurology records (if applicable), face-to-face, in-home DME evaluations
MRIs	PCP records, Orthopedic Records, Neurology Records, Physical Therapy Records
CT scans	PCP records, neurology records, other specialties as needed Cataract surgery
Cataract surgery	PCP records, ophthalmology records
Blepharoplasty	PCP records, ophthalmology records including visual fields (taped and untaped) and photographs
PET scans	PCP records, oncology records
Rehabilitation Therapy	PCP records, physical therapy records, initial assessment and treatment plan
Oxygen Equipment	PCP records, pulmonology records, O2 saturation test results
Chiropractic care	PCP records, orthopedic records (if applicable), neurology records (if applicable), x-rays/x-ray reports
Colonoscopies (including cost sharing cases)	Colonoscopy report, PCP records, gastroenterology records
Foot Care	PCP records, Podiatry records, Endocrinology records (if applicable)
Radiation Therapy/Chemotherapy	PCP records, Oncology records, lab results, surgery records (if applicable)
Bone Growth Stimulators	PCP records, orthopedic records, x-rays/x-ray reports Specialist services
Specialist services (general)	PCP records, records from specialist type at issue
Emergency Room and Ambulance Transport	ER records, ambulance trip reports, nurse's notes, ER triage/intake notes
Mental Health Services	PCP records, Psychiatry records, Psychology/Social Worker notes, Behavioral Health notes
Bariatric Surgery	PCP notes, Bariatric Surgery notes, Nutritionist notes, Endocrinology notes (if applicable)
Dental Services	Dental Records, Oral Surgery Records, Dental x-rays (preferably photo-quality digital prints)
Part B covered drugs	PCP records, requesting physician records
Part B covered drugs/Part B Step Therapy drug	Plan requirements involving step therapy analysis, enrollee physician statement, complete medical records regarding previous treatments, full Evidence of Coverage with Plan Formulary

5.3.5 CONFIRMATION OF C2C CASE RECEIPT

Submission of Reconsideration Cases and Case File Materials

Upon implementation of PACE Organization functionality for new case submission in the QIC Appeals Portal, the preferred method for receipt of all cases and case file materials is through the QIC Appeals Portal. When a case file is submitted to C2C via the QIC Appeals Portal, the PACE Organization will receive immediate on-screen confirmation that the documents have been received by C2C. This confirmation will include a tracking number.

PACE Organizations may submit cases and case file materials via hard copy mail (when appropriate) or overnight courier (see Contract Information section of this manual for

appropriate addresses). C2C does not issue a confirmation of receipt to the Plan for materials submitted through these methods.

C2C will send the appellant a timely acknowledgement letter: within 24 hours of receipt of the case file for expedited appeals and within two (2) business days of our receipt of the case file for standard appeals.

Both the appellant and the PACE Organization will receive the C2C reconsideration determination notice (see Section 6).

6. C2C RECONSIDERATION PROCESS

The purpose of this Chapter is to provide the PACE Organization with an overview of the procedures and approach that C2C follows in rendering the IRE level reconsideration. The topics addressed are:

- 6.1 C2C Case Processing Time Standards
- 6.2 Administrative Case Intake
- 6.3 Policies on Communication with PACE Organization and Appellant during Case Processing
- 6.4 Adjudicator Case Review
- 6.5 Physician Review
- 6.6 Requests to PACE Organizations for Additional Information
- 6.7 Reconsideration Determination Notices
- 6.8 Enrollee Requests for Case Files

6.1 C2C CASE PROCESSING TIME STANDARDS

C2C is responsible for completing the IRE reconsideration within the following timeframes.

<i>CASE CLASS</i>	<i>TIME STANDARD</i>
Expedited	72 hours, plus 14 calendar day extension if in enrollee's interest, or sooner if warranted by enrollee's medical condition
Standard Item or Service	30 calendar days, plus 14 calendar day extension if in enrollee's interest, or sooner if warranted by enrollee's medical condition
Standard Part B Drug	7 calendar days- no extensions are permitted for these case types
Standard Payment (Claim), Retrospective	60 calendar days

In expedited and standard item or service appeals, C2C may extend the decision timeframe by up to 14 calendar days if it is in the enrollee's interest. This 14-day extension is not permitted for standard Part B drug appeals or for standard payment (claim) appeals. C2C will notify the enrollee of the extension in writing.

The start of the adjudication time period for IRE reconsideration is the date on which the case file is received at C2C. The end of the time period is the date on which C2C mails

its reconsideration determination notice. Determinations are sent to appellants by standard first-class mail and faxed to PACE Organizations to the Decision Letter Fax Number as noted on the *PACE Reconsideration Background Form* for the specific case.

6.2 ADMINISTRATIVE CASE INTAKE

The steps in C2C administrative case intake are:

- Mail Opening and sorting of new case files
- Inquiry on CMS systems to verify beneficiary enrollment in PACE Organization
- Medicare Appeal System assignment of a random "reconsideration case number"
- Generation of acknowledgement letters, when required
- Assignment of the case to a C2C Adjudicator

Note: if the PACE Organization does not provide the enrollee's Medicare number and complete all required fields on the *PACE Reconsideration Background Data Form* (See Appendix), the errors or omissions on the *Reconsideration Background Data Form* will lead to delays in C2C's intake of the case.

6.3 POLICIES ON COMMUNICATION WITH PACE ORGANIZATION AND APPELLANT DURING CASE PROCESSING

6.3.1 ALL EVIDENCE MUST BE IN WRITING

Federal regulations define the IRE level reconsideration as a de novo determination based upon the documented case file. The IRE level reconsideration does not provide for in-person or telephonic hearings. This means that C2C may consider only such evidence as is submitted and available in the hard copy record.

Any party calling C2C is advised that the information being relayed will not be considered unless it is submitted in writing. A party is advised that he/she should follow up any "telephone testimony" immediately with written documentation.

6.3.2 COMMUNICATIONS REGARDING THE POTENTIAL IRE DETERMINATION ARE NOT PERMITTED

C2C personnel are not permitted to engage in written or phone communication with parties, where the subject of such communication is any discussion or projection of the IRE determination that C2C may make. Discussions are limited to review of the IRE process, including instructions on the procedures for submission of written information to C2C.

6.3.3 ENROLLEE SUBMISSION OF ADDITIONAL INFORMATION TO THE IRE CASE FILE

The C2C acknowledgement letter that is sent to the appellant (e.g., enrollee or valid representative), advises the appellant of their ability to submit additional information directly to C2C.

C2C may provide a PACE Organization with information that the Organization has submitted, but C2C may not provide information submitted by the enrollee. If information submitted by the enrollee is not already contained in the case file, and if the information calls into question material submitted by the PACE Organization, C2C may request clarification via a Request for Information (RFI) (See Section 6.6).

Enrollees may be less likely to submit information directly to C2C if the enrollee believes that: (1) the PACE Organization has provided the enrollee with the chance to submit evidence to the Organization and (2) the PACE Organization has advised the enrollee that the entire case file has been submitted to C2C.

6.4 ADJUDICATOR CASE REVIEW

An Adjudicator is a professional trained by C2C to: (1) manage the IRE case reconsideration and (2) make coverage determinations. Adjudicators are not permitted to make medical necessity determinations, which require physician review (See Section 6.5).

6.5 PHYSICIAN REVIEW

Pursuant to 42 CFR §422.590(h)(2), determinations of medical necessity must be made by a physician. Section 1861(r) of Social Security Act defines physicians to include a Doctor of Medicine or Osteopathy, a Doctor of Dental Surgery or of Dental Medicine, a Doctor of Podiatric Medicine, a Doctor of Optometry, and a Chiropractor. See also CMS IOM Pub. 100-01, Medicare General Information, Eligibility and Entitlement Manual, Chapter 5, Section 70 (Physician Defined).

C2C maintains an extensive national health care panel comprised of physicians and other healthcare professionals. Our physician reviewers represent more than 85 of the specialties and subspecialties recognized by the American Board of Medical Specialties (ABMS), along with hundreds of pharmacists and many other clinical experts. Our physician reviewers are located throughout the United States and include a mix of physicians who predominately practice in community rather than academic settings.

Physicians are matched to cases based upon the case clinical issue. Medical necessity decisions issued by the IRE will be made by a physician with expertise in the field of medicine that is appropriate for the disputed item, services, or Part B drug.

The physician reviewer's case file includes a copy of and, where necessary, guidance regarding any applicable Medicare National Coverage Decision (NCD), local coverage decision (LCD) or clinical guidelines. If the PACE Organization's denial decision is based on a Medicare NCD, LCD, or clinical coverage policies in Medicare manuals, PACE Organizations do not need to provide the entire manual as part of the case file but rather must identify the specific manual, chapter, and section with the relevant policy to support the Organization's decision. PACE Organizations are strongly encouraged to also include a screenshot of the relevant section or other supporting evidence. Where an Organization's medical necessity determination is based upon an Organization's specific guideline or policy, such guideline or policy as well as any relevant background evidence from the PACE Organization (including medical literature from peer reviewed publications) will be provided to the IRE's physician reviewer for consideration. PACE Organization's must include its guidelines and policies for this reason.

The physician reviewer's determination will be subject to quality reviews, including by the C2C Medical Director. Special emphasis is placed on ensuring that the physician reviewer's determination is consistent with any relevant Medicare policies or permissible and medically appropriate PACE Organization policies.

6.6 REQUESTS TO PACE ORGANIZATION FOR ADDITIONAL INFORMATION

"Request for Additional Information" (RFI) is the formal process by which C2C requests and permits the PACE Organization to supply written information to answer a question or remedy a deficiency in the reconsideration case file. The RFI process is discretionary, and C2C has no obligation to request additional information from the Organization.

6.6.1 REQUEST FOR ADDITIONAL INFORMATION IS AT C2C DISCRETION

The C2C reconsideration is designed as an "on the record" review rather than an "in person" proceeding. Therefore, the reconsideration case file must include all relevant evidence and documents used in making the PACE Organization's internal appeal determination as well as the documents and records specified in Section 5.3.

The IRE is under no obligation to seek additional information. The PACE Organization bears the burden to show why the denial is appropriate. Therefore, **missing information is reasonably construed to the enrollee's favor**. C2C may decide a case at any time based upon the information available. C2C does not overturn the Organization's denial for case file deficiencies, per se, or on an administrative basis. However, a case file deficiency typically undermines the validity of denial argument of the PACE Organization, hence missing information may result in a determination that is favorable to the appellant.

6.6.2 REQUEST FOR INFORMATION PROCESS

The process used by C2C for Request for Information is as follows:

- The Adjudicator determines the deficiency and double checks the case file to verify the information is, in fact, absent
- The Adjudicator sends a completed Request for Information Form to the fax number provided for the Case Contact on the *PACE Reconsideration Background Data Form*. For expedited cases, the Adjudicator may instead conduct the PACE Organization by phone.
- The PACE Organization Case Contact calls C2C if:
 - Questions exist about the RFI
 - The RFI deadline (See Section 6.6.3) cannot be met
- The PACE Organization develops and submits the RFI Response
- The Adjudicator reviews the RI response to determine if it is sufficient. If not:
 - Minor omissions are resolved by phone
 - Major omissions may lead to a repeat of the RFI process or may lead to C2C determination based on available documents.

6.6.3 PACE ORGANIZATION SUBMISSION OF THE RESPONSE TO A REQUEST FOR INFORMATION

The PACE Organization must expeditiously submit the requested information to C2C via the QIC Appeals Portal, fax, hard copy mail, or overnight/courier delivery.

- If hard copy delivery or fax delivery is used for an RFI response, the Organization must place the Request for Information Response Cover Sheet (see Appendix) on top of the response documents.

- If the PACE Organization places more than one RFI response in a package, separate each RFI response with the Request for Information Response Cover Sheet.

The following maximum timeframes apply for PACE Organization response to C2C Requests for Information:

Expedited Reconsiderations	Within 24 hours from date of request
Standard Item or Service Reconsiderations	Within 5 calendar days from date of request
Standard Part B Drug Reconsiderations	Within 24 hours from date of request
Standard Payment (claim) Reconsiderations	Within 5 calendar days from date of request

The deadline above is for the date of PACE Organization submission (e.g., QIC Appeals Portal, fax, or mailing) of the requested material to C2C. Expedited RFI responses and Standard Part B Drug Reconsideration RFI responses must be submitted via the QIC Appeals Portal, fax, or by overnight delivery.

C2C may expedite an RFI request if such action is necessary due to the enrollee's health.

6.6.4 PACE ORGANIZATION SUBMISSION OF ADDITIONAL INFORMATION AUTHORIZING COVERAGE OR PAYMENT FOR AN ITEM, SERVICE, OR PART B DRUG SUBSEQUENT TO PLAN SUBMISSION OF CASE AND CASE FILE TO IRE

In the rare circumstance where a PACE Organization authorizes coverage or issues payment for an item, service, or Part B drug after the Plan has submitted the case and case file documentation to the IRE for reconsideration, the Organization may take the following action:

- Expeditiously submit the additional information and supporting documentation to the IRE via the QIC Appeals Portal (*preferred*) or via fax, as directed in the applicable form in the Appendix.

Plans should include compelling evidence demonstrating that authorization or payment has been made, such as:

- Evidence of notification to the enrollee that authorization or payment has been issued by the Plan.
- A copy of the related letter sent to the enrollee or other party members.
- A screenshot or other documentation showing the authorization or payment for the item, service, or Part B drug at issue.

If the IRE determines that the information is credible, compelling, and complete, the IRE will issue a favorable decision informing the appellant that the item, service, or drug has been authorized or paid for by the PACE Organization and that no issues remain in dispute.

Note: A PACE Organization may only use this process when it is authorizing or issuing payment for all items, services, or Part B drugs in dispute for the specific case.

6.7 RECONSIDERATION DETERMINATION NOTICES

6.7.1 ISSUING A RECONSIDERATION DETERMINATION

Upon completion of its reconsideration, C2C issues a mailed "reconsideration determination" notice to the appealing party, with a faxed copy to the PACE Organization.

6.7.2 GENERAL CHARACTERISTICS OF C2C DETERMINATION NOTICES

A C2C reconsideration determination notice that overturns a PACE Organization's internal appeal determination, in whole or in part, contains an explanation of how the enrollee can obtain the disputed payment or covered service. The enrollee is directed to the PACE Organization to obtain the item or service or claim payment.

Although a C2C reconsideration determination may address or discuss medical care and treatments, the C2C reconsideration determination is not an assessment of quality of care, nor is it medical advice or instruction. A C2C determination is a ruling on the PACE Organization's obligation for coverage (payment or arrangement for a specific benefit, service, or treatment).

For any fully or partially favorable reconsideration determination, C2C also issues the PACE Organization a Notice to Comply with IRE Part C Reconsideration Determination. This document references the favorable determination notice and advises the PACE Organization of its obligation to timely effectuate the favorable decision.

6.7.3 TRANSLATION OF CORRESPONDENCE

Upon request of the enrollee or PACE Organization, C2C is required by CMS to translate its final reconsideration determination notice into the native language of the enrollee. The PACE Organization notifies C2C of the need for translation on the *Medicare Managed Care Reconsideration Background Data Form* (See Appendix).

6.7.4 PROVISION OF COMMUNICATION IN ALTERNATE FORMATS

C2C is required by CMS to arrange to provide communication in alternate formats, if needed. The PACE Organization notifies C2C of the need for alternate formats on the Reconsideration Background Data Form (See Appendix).

6.8 ENROLLEE REQUESTS FOR CASE FILES

The C2C acknowledgement letter advises the enrollee of the right to obtain a copy of the reconsideration case file from the PACE Organization and/or C2C. Under instruction from CMS, and subject to the provisions of the Privacy Act and Freedom of Information Act, C2C will release a copy of a reconsideration case file to an enrollee or other authorized individual.

C2C may release to the PACE Organization only copies of documentation the Organization has submitted in the case file.

7. POST RECONSIDERATION DETERMINATION PROCESSING

Several processes may be invoked after C2C issues its reconsideration determination notice. This Chapter provides useful information on these various post determination processes. The topics addressed are:

- 7.1 C2C Monitoring of PACE Organization Compliance with Favorable Determinations
- 7.2 IRE Reopening Process

7.1 C2C MONITORING OF PACE ORGANIZATION COMPLIANCE WITH OVERTURNED DETERMINATIONS

Compliance ("effectuation") is defined as the PACE Organization’s payment of a claim, or authorization and arrangement for an item or service or continuation of items or services (expedited, standard item or service denial, or standard Part B drug denial), as instructed in the C2C reconsideration determination notice.

7.1.1 PACE ORGANIZATION EFFECTUATION TIMEFRAMES

The following table summarizes CMS requirements for timeliness of PACE Organization effectuation:

<i>APPEAL PRIORITY</i>	<i>TIME REQUIREMENT (from receipt of notice)</i>
Expedited	Authorize or provide within 72 hours, or earlier if enrollee health dictates
Expedited Part B Drug	Authorize or provide within 24 hours, or earlier if enrollee health dictates
Standard Item or Service	Authorize within 72 hours, or as expeditiously as enrollee’s health requires but no later than 14 calendar days
Standard Part B Drug	Authorize or provide within 72 hours, or earlier if enrollee health dictates
Standard Paid Claim	Pay within 30 days

If you have questions regarding a C2C determination, please send your request to the Plan Liaison at PartC-Plan_Liaison@c2cinc.com. Please note C2C is not authorized to waive compliance with any final determination. If you feel that you cannot comply with the C2C reconsideration determination notice, you must notify your Account Manager at the CMS Regional Office.

A PACE Organization’s request for a reopening (See Section 7.2), whether granted by C2C or not, does not stay or pend the date of the compliance obligation.

7.1.2 C2C RECONSIDERATION COMPLIANCE MONITORING

CMS requires C2C to monitor PACE Organization compliance with the effectuation process, via the following procedure:

1. C2C issues the PACE Organization a copy of the reconsideration determination notice. Included with this copy is a Notice to Comply with IRE Part C

- Reconsideration Determination, that details the Organization's responsibilities, including the timeframe by which a compliance notice must be received by C2C
2. The PACE Organization is required to submit a statement attesting to compliance (effectuation) to C2C. The Statement must be submitted to C2C in accordance with timeframes noted within the Notice to Comply with IRE Part C Reconsideration Determination.
 3. C2C provides 5 days from the due date of submission for mailing time.
 4. If C2C does not receive the PACE Organization statement of compliance within 30 days, C2C reports the failure to comply to CMS. The PACE Organization is not copied on this report to CMS.

The PACE Organization statement of compliance may be in a form designed by the Organization but must contain all of the information found on the recommended Statement of Compliance Form contained in the Appendix. Please do not submit unidentified internal computer screen prints as the statement of compliance.

PACE Organization Statements of Compliance should be sent via the processes as identified in the Contact Information section of this document.

7.2 IRE REOPENING PROCESS

An IRE Reopening is an administrative procedure in which the IRE re-evaluates its reconsideration determination for the purpose of addressing an error, fraud, or information not available at the time of IRE reconsideration determination. A reopening is not an appeal right.

C2C may accept or reject a request for a reopening at its sole discretion. Within 30 calendar days of receipt of a request for reopening, C2C will make a determination as to whether or not it shall reopen a case and inform the appellant and the plan of that determination.

C2C may initiate a reopening on its own initiative. In addition, any of the parties to a reconsideration determination may request a reopening within 180 days of the decision. The reopening request must be in writing and clearly state the basis on which the request is made:

1. Error on the face of the evidence by C2C in its review,
2. Fraud, or
3. New and additional information that was not available at the time C2C made its initial determination in the case.

The process by which C2C administers and adjudicates a reopening request is similar to the reconsideration process:

1. C2C receives and logs the Reopening Request.
2. An acknowledgement letter is sent to the party requesting the reopening and PACE Organization.
3. An Adjudicator not involved in the reconsideration reviews the Reopening.
4. The Adjudicator makes a determination, incorporating a physician review if indicated.
5. A Reopening Determination Notice is issued.

6. If the Reopening Determination reverses a reconsideration (that is, the Reopening finds in fully or partially in favor of the enrollee), a Notice to Comply with IRE Part C Reconsideration Determination is also issued to the PACE Organization. The Organization is then responsible for "effectuation" per the discussion of compliance above.

A PACE Organization's request for a reopening does not relieve the Organization of the burden of compliance, and reporting of compliance, within the required timeframes (See Section 7.2). The Organization is relieved of this burden if the Organization obtains a Reopening Reversal (of a Favorable reconsideration) prior to the PACE Organization compliance date. The Organization is not relieved of the burden of compliance with the original favorable reconsideration if the Organization receives a Reopening Reversal after the original compliance date.

7. C2C's contract with CMS allows 120 days for the processing of Reopening cases. In many cases, especially those requiring physician review, the full timeframe may be required.

8. RECONSIDERATION DATA

C2C extracts numerous data elements from submitted reconsideration case files and provides reports to CMS based on the collected data. This Section discusses the related data systems and how the collected information is used within the reports. The topics addressed are:

- 8.1 Medicare Appeals System (MAS)
- 8.2 PACE Organization Monitoring Reports
- 8.3 Using the C2C Website to Track Timeliness and Effectuation

8.1 MEDICARE APPEALS SYSTEM (MAS)

C2C utilizes the Medicare Appeal System (MAS) to support administration of the reconsideration process. Data is obtained and entered into the MAS from the following sources:

- CMS data systems, which provide enrollee and PACE Organization identifying information.
- *PACE Reconsideration Background Data Form*, from which certain data fields completed by the PACE Organization are entered, as given into the MAS.
- Adjudicator abstraction of information from other reconsideration case file documents.

In addition to providing data to C2C for general program administration, MAS data is relevant to PACE Organizations in the following ways:

- CMS obtains reports, based upon MAS data, to monitor certain aspects of PACE Organization compliance with appeal requirements.
- CMS publishes Quarterly Part C Reconsideration Appeals Data Fact Sheets on its website: <https://www.cms.gov/medicare/appeals-grievances/managed-care/review-part-c-independent-entity>.

8.2 PACE ORGANIZATION MONITORING REPORTS

C2C reports information to CMS related to:

- Timeliness of PACE Organization service determination and internal appeals
- PACE Organization effectuation of IRE overturned reconsideration determinations

It is important to note that C2C provides the above reports to CMS Central and Regional Offices to advise those offices of potential non-compliance. CMS personnel determine how such reports should be used in discharge of their PACE Organization monitoring function.

Typically, CMS personnel will contact the PACE Organization if a significant issue (for example, outlier) or pattern appears to exist and will provide the PACE Organization with the opportunity to research the case(s) more thoroughly.

However, as will be explained below, the source of the reported compliance data is primarily the PACE Organization itself—specifically entries made to the *PACE Reconsideration Background Data Form* (or via the online form in the QIC Appeals Portal) by the PACE Organization. **It is imperative that the PACE Organization carefully and accurately complete the form.**

Timeliness of PACE Organization - Service Determination and Internal Appeal

The *PACE Reconsideration Background Data Form* (See Appendix) requires the Organization to:

- Classify the case by priority (expedited, standard item or service, standard Part B drug, standard payment)
- Enter "date of receipt" and "date of completion" of the service determination and internal appeal decision
- Enter requests for expedited processing and related PACE Organization decision
- Indicate if a 14-day extension was taken "in the enrollee's interest" (this extension is not applicable to standard payment (claim) and standard Part B drug appeals).

This data is used to calculate the time interval within which the PACE Organization's service determination and internal appeal should occur and compares this interval with the actual timeliness reported by the Organization. A variety of reports that measure PACE Organization timeliness are submitted to CMS using these calculations. This set of reports relies upon the information exactly as given by the PACE Organization on the Reconsideration Background Data Form. Consequently, PACE Organization errors or omissions on this form will result in reporting of either missing data or cases outside of timeframe compliance.

In addition, the C2C adjudicators compare the contents of the case file (for example, notices and correspondence) to the data reported by the PACE Organization on the *PACE Reconsideration Background Data Form* (or portal submission). If the Adjudicator determines that an error or omission exists on the Reconsideration Background Data Form, this error or omission is, if possible, corrected and reported separately. C2C uses

this information to report "discrepancies" with respect to Organization reported timeliness to CMS.

Timeliness of Effectuation Compliance

Using the PACE Organization's report of effectuation to C2C, we report to CMS listings of cases without compliance notice and statistics on effectuation compliance.

8.3 USING THE C2C WEBSITE TO TRACK TIMELINESS AND EFFECTUATION

In order to allow PACE Organizations to proactively monitor the cases that they have sent to C2C for processing, we have developed a website that allows Medicare Health Plans and PACE Organizations to access timeliness and compliance data in via our Effectuation Status Lookup tool, available on the Part C QIC website:

<https://partappeals.c2cinc.com/>. This website is updated daily and is current as of the close of business on the previous business day.

8.3.1 TIMELINESS DATA

PACE Organizations can access timeliness data from the Part C QIC website (<https://partappeals.c2cinc.com/>) by accessing the Appeals Status Lookup. Once selected, this tool gives PACE Organizations multiple options for searching for data, for example by a particular contract number or case number. It also allows Organizations to limit the search by, for example, the date that C2C receives the case or the date that C2C renders its decision. Once the limiting information is entered into this search box, a list of data results will appear. The resulting data list can be exported into either an Excel or .csv file.

8.3.2 EFFECTUATION DATA

PACE Organizations can access effectuation data from the Part C QIC website (<https://partappeals.c2cinc.com/>) by accessing the Effectuation Status Lookup. Once selected this tool gives the PACE Organization the ability to monitor effectuation and compliance. Plans can search the data on the website and monitor which of their cases have been found favorable or partially favorable by the IRE and determine if C2C has received the PACE Organization's attestation of compliance with the related effectuation. As with timeliness data, PACE Organizations can limit the search by various data points and export the resulting data into MS Excel or a .csv format.

This data provides PACE Organizations with decision disposition and information regarding whether the Plan compliance attestation has been received and recorded by C2C.

8.3.3 DATA DISCREPANCIES

If a PACE Organization notices that there is no compliance data entered for a case where they have sent compliance information to C2C, or that timeliness data listed on the website appears to be inaccurate, C2C can investigate that discrepancy. With either the timeliness or effectuation data, if a PACE Organization has a question about a data element or wants to report a discrepancy, they can send an email to the Plan Liaison at PartC-Plan_Liaison@c2cinc.com. This email box is continuously monitored, and questions are answered promptly.