DHCS AUDITS AND INVESTIGATIONS

CONTRACT AND ENROLLMENT REVIEW DIVISION

SAN DIEGO SECTION

REPORT ON THE FOCUSED MEDICAL REVIEW OF TOTAL LONGTERM CARE, INC. DBA INNOVAGE GREATER CALIFORNIA PACE INLAND EMPIRE FISCAL YEAR 2023-24

Contract Number: 20-10149

Audit Period: January 1, 2023 — December 31, 2023

Dates of Audit: March 18, 2024 — March 19, 2024

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I. INTRODUCTION

Total Longterm Care, Inc. dba InnovAge Greater California PACE Inland Empire (PACE Organization or "PO") is a provider of the Program of All-Inclusive Care for the Elderly (PACE) serving approved zip codes in San Bernardino and Riverside counties. The PACE model of care provides a comprehensive medical and social delivery system using an interdisciplinary team approach in a PACE center that provides and coordinates preventive, primary, acute, and long-term care services. The PO began contracting with the California Department of Health Care Services (DHCS) to administer the PACE program on February 1, 2014.

The PO is a subsidiary of InnovAge Holding Corp., which established its first PACE center in Denver, Colorado in 1990 as a non-profit. On May 13, 2016, InnovAge Holding Corp., was formed as a for-profit corporation. InnovAge Holding Corp. is headquartered in Denver, Colorado, and operates 17 PACE centers in California, Colorado, New Mexico, Pennsylvania, and Virginia. InnovAge Holding Corp. operates three PACE Organizations in California located in Crenshaw (serves zip codes in Los Angeles County), Inland Empire (serves zip codes in Riverside and San Bernardino Counties), and Sacramento (serves zip codes in El Dorado, Placer, Sacramento, San Joaquin, Sutter, and Yuba Counties).

As of March 2024, the InnovAge PACE Organizations operating in California served approximately 330 participants in Riverside County, 839 participants in San Bernardino County, 361 in the Sacramento area, and 24 in Los Angeles County.

DHCS conducted audits of InnovAge Holding Corp.'s Sacramento PACE Organization and issued audit findings on May 10, 2021, and October 2, 2023. Additionally, the federal Centers for Medicaid and Medicaid Services (CMS) conducted an audit of the Sacramento PACE Organization issuing its final report findings on October 2, 2023. Based on the deficiencies found, DHCS suspended participant enrollment from September 30, 2021, to May 1, 2023. DHCS also suspended applications for operating new PACE Organizations effective January 7, 2022, which was lifted on May 1, 2023 and reimposed this suspension on January 23, 2024.

In early 2024, DHCS received multiple complaints related to several PACE program areas where the PO may not be meeting contractual and regulatory requirements, and as a result, potentially impacting the health and safety of PACE participants. On January 23, 2024, DHCS informed the PO of its concerns related to the administration of the PACE

program. These concerns included but were not limited to: Transportation; Marketing and Enrollment; Utilization Management (UM) and Past Due Orders; Grievances; Service Delivery Requests (SDRs); and Medication and Supplement Disbursement.

DHCS subsequently conducted a focused medical review of the PO to assess the PO's ability to provide adequate care, ensure timely service, and adhere to the PO's contract and PACE program requirements, including state and federal laws, regulations, and guidance in accordance with Code of Federal Regulations (CFR), Title 42, section 460.192.

II. EXECUTIVE SUMMARY

This report presents the findings of the DHCS' focused medical review for the period of January 1, 2023, through December 31, 2023. The focused medical review onsite visit was conducted from March 18, 2024, through March 19, 2024. The focused medical review consisted of document review, verification studies, and interviews with PO representatives.

An Exit Conference with the PO was held on October 15, 2024. The PO was allowed 15 calendar days from the date of the Exit Conference to provide supplemental information addressing the draft report findings. The PO submitted a response after the Exit Conference. The results of the evaluation of the PO's response are reflected in this report.

The focused medical review evaluated the following areas: Transportation, Utilization Management and Past Due Orders, Marketing and Enrollment, Grievance/SDR, and Medication and Supplement Disbursement.

The summary of the findings by category follows:

Transportation

The PO's transportation personnel must have training and working knowledge of policies and procedures regarding participant safety during transportation. When there are incidents involving participants, the PO's employees should follow appropriate emergency protocols. Additionally, transportation vans must be operated by a certified driver and attendant. The PO did not maintain current and valid records for its transportation personnel, including CPR or First Aid certifications and driver's licenses.

Utilization Management and Past Due Orders

The PO must process primary care physician (PCP) orders and referrals in a timely manner, especially those referring participants out to specialists. When processing orders and referrals, the PO should use a set of written criteria or guidelines for utilization review based on sound medical evidence. In addition, the PO should clearly document the reasons for its decisions. The PO did not have written criteria or guidelines, nor did it clearly document the reasons for denying prior authorizations (PAs).

When the PO has made a decision regarding an order or referral, it must provide notification to the requesting provider or participant. The PO did not provide notification regarding orders or referrals that were denied or delayed.

Furthermore, the PO's UM program must include an established specialty referral system to track and monitor referrals including PA requests. The PO did not document nor track all denied specialty referrals across all care settings.

The PO must also have a physician available 24 hours a day, seven days a week to coordinate transfer of care for participants, authorize medically necessary post stabilization services, and for general communication with emergency department (ED) personnel. The PO did not utilize physicians for the authorization of medically necessary post-stabilization services and general communications with ED personnel.

Lastly, the PO must ensure the delivery of preventive services and medically necessary diagnostic and treatment services for participants. The PO did not complete tuberculosis (TB) screenings, clinical breast exams, mammograms, cervical cancer screenings, nor colon cancer screenings for its participants. The PO failed to provide services that were accessible and/or adequate to meet the needs of its participants.

Grievance and Service Determination Requests

The PO is required to process grievances and SDRs, especially those concerning the health and safety of its participants, in a timely manner. When the interdisciplinary team (IDT) receives an SDR, it must make a decision and notify the participant or their designated representative within three calendar days. If the IDT extends the timeframe for the SDR, it must notify the participant or their designated representative. The PO did not process requests made by participants as SDRs. In addition, the PO did not provide timely notification of SDR decisions nor provide notification to participants if their SDR had a time extension.

Additionally, the PO is required to provide the participant with timely notice of the resolution of their SDR. A PO that does not provide timely notice nor furnishes the services required by the revised plan of care constitutes an adverse decision. The participant’s request must then be automatically processed by the PO as an appeal. The PO did not process unresolved SDRs as automatic appeals.

Medication and Supplement Disbursement

The PO must ensure that its participants receive medication and/or adequate food in a timely manner. The PO's PA procedures should include qualified health care

professionals who supervise medication and supplement orders and review all denials that are made. The PO made service denials for medications that were not reviewed by a qualified physician.

III. SCOPE/AUDIT PROCEDURES

SCOPE

The DHCS Audits and Investigations, Contract and Enrollment Review Division, conducted this targeted medical review to ascertain whether the administration of the PACE program is compliant with federal and state laws, applicable regulations and guidelines, and the state Contract.

PROCEDURE

DHCS conducted a focused medical review of the PO to review concerns raised by multiple complainants. The focused medical review included a review of the PO's policies for providing services, the procedures used to implement the policies, and verification studies of the implementation and effectiveness of the policies. Documents were reviewed, and interviews were conducted with PO staff.

The following verification studies were conducted:

Transportation

Transportation Personnel: 10 driver records were reviewed to verify personnel requirements were met.

Marketing and Enrollment

Enrollments & Disenrollments: 10 participant enrollments and 14 participant disenrollments were reviewed for appropriate processing.

Utilization Management and Past Due Orders

Orders: 13 participant records were reviewed to verify orders were appropriately processed for medically necessary services.

Pharmacy PA: 10 participant records were reviewed to verify medications were appropriately ordered and recommended.

Grievance and Service Determination Requests

There were no verification studies conducted for the audit review. Grievance Procedures: 9 Quality of Service and 11 Quality of Care grievance cases were reviewed for timely

resolution, appropriate response to complainant, and submission to the appropriate level for review. 12 participant calls from inquiry logs were reviewed for appropriate classification and processing.

SDRs: 10 participant records were reviewed to verify SDRs were processed appropriately and timely.

The results of the review are outlined in this report.

COMPLIANCE AUDIT FINDINGS

Transportation

1. Transportation Personnel Records

The PO must train all transportation personnel in managing the special needs of participants and handling emergency situations. *(Contract, Exhibit A, Attachment 10, Provision 6; Code of Federal Regulations (CFR), Title 42, section 460.76(d))*

The PO's transportation vans shall be operated by a certified driver and attendant who possess a current California driver license or a current California Ambulance Driver Certificate; be at least 18 years of age; possess at least a current American Red Cross Standard First Aid and Personal Safety Certificate or equivalent; and has passed a physical examination within the past two years and possess a current Department of Motor Vehicle form DL-51, Medical Examination Report. Additionally, persons registered as a sex offender; habitually or excessively uses or is addicted to narcotics or dangerous drugs; has been convicted in the preceding seven years of a felony offense relating to the use, sale, possession or transportation of narcotics, drugs or alcohol; or habitually or excessively uses intoxicating beverages cannot act in the capacity of a driver or attendant. *(Contract, Exhibit A, Attachment 1 A1, Definitions, Non-Emergency Medical Transportation; California Code of Regulations (CCR), Title 22, sections 51231.1 and 51231.2)*

Additionally, the PO's staff members must receive in-service training in first aid and in cardiopulmonary resuscitation within the first six months of employment. *(Contract, Exhibit A, Attachment 1 A1, Definitions, Pace Organization; PACE Program Agreement Number H6079, Article V, Requirements of Laws and Regulation; CCR, Title 22, section 78413(e))*

Finding: The PO does not maintain current and valid records for its transportation personnel, including CPR or First Aid certifications and driver's licenses.

The review revealed that 34 of 39 transportation personnel did not possess a current American Red Cross Standard First Aid and Personal Safety Certificate or equivalent. In addition, the review also revealed the following:

- 3 of 39 drivers with an expired Department of Motor Vehicle form DL-51, Medical Examination Report

- 2 of 39 drivers without a drug screening
- 1 of 39 drivers with an expired California driver's license

In a written response, the PO stated that CMS guidance only requires PACE staff rendering participant care to be CPR certified. The PO also stated that they were only informed by DHCS of this requirement in the past month. Additionally, in an interview, the PO stated it was unaware of this state regulatory requirement for its personnel until the October 2, 2023, review of the PO's Sacramento center was conducted.

The PO also acknowledged that personnel records on file were not adequately updated due to high turnover in its human resources department. Subsequently, in October 2023, the PO entered into an agreement with a contractor for the management of personnel records. Per the agreement, the contractor provides Department of Transportation risk management, continuous MVR (motor vehicle report) monitoring, and drug/alcohol screening. However, the agreement did not delineate the monitoring of CPR or first aid certifications. The PO's policy, *Staffing* (published September 2022), also does not include CPR or first aid certification as a requirement for its transportation personnel.

If the PO does not maintain current and valid records, its transportation personnel may not be qualified to service participants. Additionally, personnel without a current American Red Cross Standard First Aid and Person Safety Certificate or equivalent certification may not handle emergency situations appropriately and could result in negative health outcomes for participants.

Recommendation: The PO's compliance and oversight program should ensure that their internal monitoring, training, and internal audit processes are aligned with contractual requirements and are established to proactively identify potential deficiencies, implement corrective actions, and maintain compliance. The PO's compliance and oversight program policies and procedures should be reviewed and updated for effectiveness.

The PO should revise policy and procedures to include first aid certification as a requirement for transportation personnel and to ensure current licenses and certifications are tracked and monitored which include immediately updating all transportation personnel records to reflect that all transportation personnel have current certification for CPR and First Aid, valid California driver's license and drug screenings as well as regular monitoring methodology.

Additionally, the PO should develop and implement training immediately and at regular intervals.

COMPLIANCE AUDIT FINDINGS

Utilization Management and Past Due Orders

1. Prior Authorization Review Criteria

PA involve a formal process that requires a health care provider to obtain advance approval to provide specific services or procedures, or the process by which an IDT approves a member to receive a specific service or procedure. The IDT is responsible for granting approval to specific, non-emergency medical services in advance of rendering such services. *(Contract, Exhibit E, Attachment 1 A1; CFR, Title 42, section 460.102(d)(1)(ii))*

The PO shall ensure that its PA, concurrent review, and retrospective review procedures shall meet the requirement of having a set of written criteria or guidelines for utilization review that is based on sound medical evidence. The written criteria or guidelines is consistently applied, regularly reviewed, and updated. *(Contract, Exhibit A, Attachment 5 A1, Provision 2(C))*

Finding: The PO does not have a set of written criteria or guidelines for utilization review that is based on sound medical evidence.

In an interview, the focused review team inquired about the criteria utilized to determine the denial of services requested by contracted specialists or by participants. The PO stated that services are not denied, but instead declined at the discretion of the IDT. Furthermore, during the interview, the PO could not confirm that the decisions of the IDT adhered to Medi-Cal criteria, and it could not cite any evidence-based guidelines that informed their decision-making.

The PO stated its *Service Determination Requests* policy is the written criteria and guidelines for utilization review. However, this policy does not reference any written criteria or guidelines based on sound medical evidence to ensure they are consistently applied, regularly reviewed, and updated.

During the review, the PO continued to deny the contract definition of PA, which is the process by which an IDT approves a participant to receive a specific service or procedure. Subsequently, the PO does not have established PA review procedures and relies on a policy for a different request type as its guidelines.

If the PO does not reference established criteria when making medical determinations, there is a risk that participants will be inappropriately denied or approved services which could lead to over and underutilization, as well as adverse health outcomes.

Recommendation: The PO's compliance and oversight program should ensure that their internal monitoring, training, and internal audit processes are aligned with contractual requirements and are established to proactively identify potential deficiencies, implement corrective actions, and maintain compliance. The PO's compliance and oversight program policies and procedures should be reviewed and updated for effectiveness. Maintaining compliance with utilization management requirements is fundamental to operating a PO.

The PO should develop policies and procedures containing written criteria or guidelines for utilization review that are based on sound medical evidence and are consistently applied, regularly reviewed, and updated. The PO must establish training protocols and ensure all members of the IDT team receive training and regularly evaluate policies and procedures for effectiveness and revise as needed.

2. Decision Notifications

The PO must notify the requesting provider or participant of any decision to deny, approve, modify, or delay a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested. The notice to the provider may be provided orally or in writing. Notice to the participant shall be in writing. *(Contract, Exhibit A, Attachment 5 A1, Provision 2(I))*

Finding: The PO did not notify the requesting provider or the participant of service denials or delays.

The focused review team conducted three verification studies for orders, pharmacy PAs, and SDRs; each involved the review of participant's medical records. A total of 34 participant medical records were reviewed, with 7 participant records evidencing a denial or delay in services that were not communicated orally or in writing to the requesting provider or participant.

A review of the PO's policy, *Order Lifecycle – Standards of Practice* (effective October 2023), states that PCPs can place an order within the electronic medical record (EMR) system and based on the date of the order, schedulers will schedule appointments. If an appointment cannot be scheduled, the scheduler documents the attempts in the EMR and notifies the PCP, who will then determine the next steps based on participant need.

The policy does not delineate utilization review requirements for the PCP orders, such as assessment for medical necessity and notifying the participant in writing.

During the review, the PO continued to deny the contract definition of PA, which is the process of an IDT approving a participant to receive a specific service or procedure. Instead, the PO defaults to its own processing procedures (also known as 'order life cycle') that do not meet the contractual requirements for PA and utilization review, including appropriate notification to the provider and participant.

If the requesting provider or participant is not informed of denials or delays to medically necessary services, participants may not receive appropriate care for their healthcare needs. This can subsequently result in adverse health outcomes.

Recommendation: The PO's compliance and oversight program should ensure that their internal monitoring, training, and internal audit processes are aligned with contractual requirements and are established to proactively identify potential deficiencies, implement corrective actions, and maintain compliance. The PO's compliance and oversight program policies and procedures should be reviewed and updated for effectiveness. The PO should revise and implement procedures to notify requesting providers and participants of service denials or delays and, as noted, ensure policy and procedures are revised to align with contractual requirements. The PO must establish training protocols and ensure all members of the UM team responsible for communicating service denials or delays receive training and the PO should regularly evaluate policies and procedures for effectiveness and revise as needed.

3. Specialty Referral System

The PO is responsible to ensure the UM program includes an established specialty referral system to track and monitor referrals regarding PA through the PO. The system shall include authorized, denied, deferred, or modified referrals, and the timeliness for the referrals. This specialty referral system should include non-contracting providers. The PO shall ensure that all contracting healthcare practitioners are aware of the referral processes and tracking procedures. *(Contract, Exhibit A, Attachment 5 A1, Provision 1(F))*

Finding: The PO did not track and monitor all denied specialty referrals across all care settings.

The focused review team requested reports generated by the PO's referral tracking system, including referrals to out-of-network providers. The PO submitted a PCP orders list for the review period, but it did not include the tracking of denied referrals.

The PO's policy, *Order Lifecycle* (effective July 2023), states that the PO's system provides orders tracking reporting on a weekly, monthly, and quarterly basis for center leadership's review to monitor orders for timely completion. Despite the generation of frequent monitoring reports, the PO did not provide further evidence of it tracking denied referrals. Furthermore, the focused review team's examination of the UM meeting minutes indicated that the review of specialty referral utilization patterns that are specific to the San Bernardino center were not discussed in routine UM meetings.

The PO does not have a specific UM program for its San Bernardino center that ensures appropriate processes are used for the review and approval of medically necessary covered services, as contractually required.

When the PO does not track authorizations, it could result in missed opportunities to detect and correct the underutilization of services. Without tracking specialty referrals, the PO risks delaying medically necessary care for participants. This can potentially worsen a participant's health outcome by delaying the diagnosis and treatment of serious conditions.

Recommendation: The PO's compliance and oversight program should ensure that their internal monitoring, training, and internal audit processes are aligned with contractual requirements and are established to proactively identify potential deficiencies, implement corrective actions, and maintain compliance. The PO's compliance and oversight program policies and procedures should be reviewed and updated for effectiveness. The PO should establish a specialty referral system that tracks and monitors the center's denied referrals across all care settings. The PO should develop and implement policies relevant to the specialty referral system and regularly evaluate policies and procedures for effectiveness and revise as needed. The PO must establish training protocols and ensure all members of the UM and referral team receive training on the system.

4. Participant Assessments

PA involve a formal process that requires a health care provider to obtain advance approval to provide specific services or procedures, or the process by which an IDT approves a member to receive a specific service or procedure. The IDT is responsible for granting approval to specific, non-emergency medical services in advance of rendering such services. *(Contract, Exhibit E, Attachment 1 A1; CFR, Title 42, section 460.102(d)(1)(ii))*

The PO must conduct an initial comprehensive assessment by the IDT on each participant, periodic reassessments, and unscheduled reassessments as required by CFR, Title 42, section 460.104. The comprehensive assessment must include an evaluation of the participant's current health status and treatment needs. *(Contract, Exhibit A, Attachment 10 A1, Provision 3; CFR, Title 42, section 460.104)*

The PO shall ensure that the performance of the initial complete history and physical exam for participants includes, but is not limited to, blood pressure measurements, height, weight, cholesterol measurement, a clinical breast examination, a mammogram, a pap smear, and a TB screening. *(Contract, Exhibit A, Attachment 10 A1, Provision (4)(A))*

In addition, the PO shall cover and ensure the delivery of all preventative services and medically necessary diagnostic and treatment services for participants. The PO shall implement and maintain *The Guide to Clinical Preventive Services*, a report of the U.S. Preventive Service Task Force (USPSTF) as the minimum acceptable standard for Participant Preventive Health Services. The preceding are a core set of preventive services that shall be provided to all asymptomatic, healthy participants, age 21 and older. *(Contract, Exhibit A, Attachment 10 A1, Provision 4(B)(1))*

The USPSTF recommends screening for colon cancer in all adults aged 50 to 75 years.

Finding: The PO did not complete TB screenings, clinical breast exams, mammograms, cervical cancer screenings, and colon cancer screenings for its participants.

The focused review team conducted three verification studies (orders, pharmacy PAs, and SDRs) for UM, each involved the review of participant's medical records. A total of 34 participant's medical records were reviewed. The review found the following:

- Among new enrollees receiving an Initial Health Assessment, two did not receive a TB screening.
- Among women undergoing a physical exam, ten participants did not have a clinical breast examination documented in their medical records. Furthermore, there is no indication in the record that the exams were offered and subsequently declined by the participant.
- Among women eligible for a mammogram, two participants did not have a documented mammogram in the past 1-2 years. There was no documentation that a mammogram was offered and subsequently declined by the participant.
- Among those eligible for a colon cancer screening, four participants did not have an up-to-date colon cancer screening documented. There was no

documentation that a colon cancer screening was offered and subsequently declined by the participant.

- Among women eligible for a cervical cancer screening, two participants did not have an up-to-date cervical cancer screening documented. There was no documentation that a cervical cancer screening was offered and subsequently declined by the participant.

When the PO does not render covered preventative health services, it can lead to the underutilization of medically necessary services, which can result in harm to the participant's overall health.

Recommendation: The PO's compliance and oversight program should ensure that their internal monitoring, training, and internal audit processes are aligned with contractual requirements and are established to proactively identify potential deficiencies, implement corrective actions, and maintain compliance. The PO's compliance and oversight program policies and procedures should be reviewed and updated for effectiveness. Ensuring PACE participants receive preventive care benefits in accordance with contractual provisions is fundamental to operating a PO.

The PO should develop and implement policies and procedures to ensure participants receive all covered preventative services and medically necessary diagnostic and treatment services. The PO should establish protocols to identify and conduct outreach to PACE participants who are in need of preventive care services. The PO must establish training protocols and ensure relevant personnel receive trainings on updated policies and procedures and protocols.

5. Physician Availability

The PO shall have a PACE or contracting physician available 24-hours-per-day, 7-days-a-week to coordinate the transfer of care of a participant whose emergency condition is stabilized, to authorize medically necessary post stabilization services, and for general communication with emergency department personnel. *(Contract, Exhibit A, Attachment 6 A1, Provision 10)*

Finding: The PO employed the use of nurse practitioners for the authorization of medically necessary post-stabilization and general communication with emergency department personnel.

During an interview, the PO stated that during after-hours, nurse practitioners act independently, and their decisions are reviewed the following morning by the IDT, which

may include physicians. The PO was unaware that a physician should be available 24-hours-per-day, 7-days-a-week to coordinate and authorize care.

In an interview and written response, the PO stated that its nurse practitioners can independently act as PCPs on an IDT to contractually fulfill all roles that are relegated only to qualified physicians.

If the PO does not have qualified staff performing authorization of post-stabilization services following emergency department visit, it may lead to poor health outcomes for participants.

Recommendation: The PO's compliance and oversight program should ensure that their internal monitoring, training, and internal audit processes are aligned with contractual requirements and are established to proactively identify potential deficiencies, implement corrective actions, and maintain compliance. The PO's compliance and oversight program policies and procedures should be reviewed and updated for effectiveness.

The PO should develop and implement policies and procedures to ensure that post-stabilization care services following an emergency department visit are authorized by a qualified physician.

COMPLIANCE AUDIT FINDINGS

Grievances and Service Determination Requests

1. Service Determination Request Processing

The PO must have formal written procedures for identifying and processing SDRs. A SDR includes a request to initiate a service; a request to modify an existing service, including to increase, reduce, eliminate, or otherwise change a service; or a request to continue coverage of a service that the PO is recommending be discontinued or reduced. *(CFR, Title 42, sections 460.121(a) & (b); Contract, Exhibit A, Attachment 1 A1, Definitions, Pace Organization; PACE Program Agreement Number H6079, Article V, Requirements of Laws and Regulation)*

SDRs may be made by the participant, the participant's designated representative, or the participant's caregiver. An individual may make an SDR either orally or in writing. The request may also be made to any employee or contractor of the PO that provides direct care to a participant in the participant's residence, the PACE center, or while transporting participants. *(CFR, Title 42, sections 460.121(c) & (d); Contract, Exhibit A, Attachment 1 A1, Definitions, Pace Organization; PACE Program Agreement Number H6079, Article V, Requirements of Laws and Regulation)*

If a participant of the IDT is able to approve the SDR in full at the time the request is made, the PO must fulfill all of the following: (a) notice of the decision to approve an SDR requirement, (b) effectuation requirements to provide the approved service as expeditiously as the participant's condition requires, and (c) recordkeeping requirements to document, track, and maintain records related to processing of SDRs. *(CFR, Title 42, section 460.121(e)(2)(i); Contract, Exhibit A, Attachment 1 A1, Definitions, Pace Organization; PACE Program Agreement Number H6079, Article V, Requirements of Laws and Regulation)*

The PO's policy, *Service Determination Request* (effective September 2023), states the PO will ensure regulatory compliance, timely resolution of requests by a participant or his/her designated representative to initiate, modify, or continue a particular service. SDRs can be made by participants, their designated representatives, or caregivers for any type of PACE covered services, items, or drugs. The requests may relate to a participant's medical, emotional, or social needs. PACE services include, but are not limited to, hearing aids, dentures, power mobility devices, nutritional supplements, and

services such as increasing day center days, initiation of or an increase in home care services or rehabilitation services, among others.

Finding: The PO did not process participant requests as service determination requests.

The focused review team conducted three verification studies (orders, pharmacy PAs, and SDRs) for UM, each involved the review of participant's medical records. A total of 34 participant's medical records were reviewed which found the following:

- A participant declined all medications, including life-saving medications, for their chronic conditions in favor of a holistic health approach to their treatments. The participant's PCP discontinued all medications; however, it was not processed as a SDR and there was no discussion about hospice care. The PO did not meet the effectuation and recordkeeping requirements for this participant's SDR. The participant has a medical durable power of attorney in place. The participant's representative was not made aware of this change in the participant's plan of care. Subsequently, the participant died within months of discontinuing their medications.
- A participant's caregiver requested an increase in center days. There was no indication that this was processed as a SDR. The request was immediately approved. However, the PO did not meet effectuation and recordkeeping requirements.
- A participant requested a colonoscopy for colon cancer screening due to having a family history of related cancer. Instead, an order for a fecal immunochemical test was placed for the participant. This request was not processed as a SDR.
- A participant requested an ophthalmology consult, along with requesting their medication be changed from Tramadol to Norco. Neither request was processed as a SDR.
- A participant expressed their frustrations with mental health care and requested to see a psychiatrist in person instead of through telehealth. The request was not processed as a SDR.

The PO did not regularly inform its participants of the SDR process. It was the discretion of the participant's social worker to provide reminders about the SDR process. Additionally, a review of the PO's website does not provide information regarding SDRs.

If participants are not informed of the SDR process, participants may be prevented from exercising their right to participate in decision-making about their care.

Recommendation: The PO's compliance and oversight program should ensure that their internal monitoring, training, and internal audit processes are aligned with contractual requirements and are established to proactively identify potential deficiencies, implement corrective actions, and maintain compliance. The PO's compliance and oversight program policies and procedures should be reviewed and updated for effectiveness.

The PO should ensure the PO processes participant requests as SDRs. The PO must establish training protocols and ensure relevant personnel receive trainings on the SDR process including the rights that are afforded to participants through the SDR process.

2. Service Determination Request Notifications

When the interdisciplinary team receives a service determination 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 three calendar days after the date the interdisciplinary team receives the request. *(CFR, Title 42, Section 460.121 (i); Contract, Exhibit A, Attachment 1 A1, Definitions, Pace Organization; PACE Program Agreement Number H6079, Article V, Requirements of Laws and Regulation)*

When the interdisciplinary team extends the timeframe, it must notify the participant or their designated representative either orally or 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. *(CFR, Title 42, Section 460.121 (i)(2); Contract, Exhibit A, Attachment 1 A1, Definitions, Pace Organization; PACE Program Agreement Number H6079, Article V, Requirements of Laws and Regulation)*

The PO's policy, *Service Determination Requests* (effective September 2023), states that if the IDT approves a request, an appropriate participant of the IDT must notify the participant, designated representative, or caregiver verbally or in writing within three calendar days or eight calendar days if an extension was warranted. Verbal notifications must be documented in the electronic medical record and explain the condition(s) of approval, if any, in understandable language, including when the participant expects to receive the approved item, service, or payment.

Additionally, the *Service Determination Requests* policy states that if an extension is requested or needed for an SDR, the PO must complete a verbal or written notice to the

participant. The notice must be no later than 24 hours after the IDT decides an extension is warranted.

Finding: The PO exceeded SDR notification timeframe requirements and did not notify participants of timeframe extensions.

During the review period, the PO's records revealed it only documented a total of 67 SDRs. Of these SDRs where a decision was communicated orally, there were 10 cases where the PO provided notification after three calendar days. Additionally, a verification study of 10 SDR samples revealed the following:

- 2 samples where SDRs were reviewed by the IDT in four calendar days.
- 1 sample where an extension was made, but the PO did not notify the participant or their caregiver of the timeframe extension.
- 1 sample where a participant was notified two months after a decision had been made by the PO.

In an interview, the PO stated that its staff was not familiar with the SDR process and would require further education and training. The PO also cited turnover with staff.

When the PO does not notify its participants of SDR decisions in a timely manner, it may deprive the participant of information that could affect their healthcare decisions.

Recommendation: The PO's compliance and oversight program should ensure that their internal monitoring, training, and internal audit processes are aligned with contractual requirements and are established to proactively identify potential deficiencies, implement corrective actions, and maintain compliance. The PO's compliance and oversight program policies and procedures should be reviewed and updated for effectiveness.

The PO should develop procedures to ensure participants are notified of decisions and extension requests within required timeframes. The PO must establish training protocols and ensure relevant personnel receive trainings on the SDR process including the rights that are afforded to participants through the SDR process

3. Service Determination Requests Without a Decision

If the IDT fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PO as an appeal in accordance with Title 42, CFR, Section 460.122.

(CFR, Title 42, section 460.121(l); Contract, Exhibit A, Attachment 1 A1, Definitions, Pace Organization; PACE Program Agreement Number H6079, Article V, Requirements of Laws and Regulation)

The PO's policy, *Service Determination Requests* (effective September 2023), states that if the initial service determination request is not brought to the full IDT within three calendar days, the request will be processed as an automatic appeal.

Finding: The PO failed to process unresolved SDRs as automatic appeals.

During the review period, the PO's records revealed it only documented a total of 67 SDRs, in which four SDRs did not have a decision. When an SDR is not processed, this constitutes an adverse decision, and it must be processed as an appeal.

In an interview, the PO's Director of Compliance acknowledged the requirement to process SDRs without a decision as an appeal. However, a review of the PO's appeal log found that none of the four SDRs were logged. The PO subsequently stated that its staff was not familiar with the SDR process and would require further education and training.

When the PO does not notify participants in a timely manner of the status of SDR decisions, participants may be deprived of information that could affect their health care decisions. When the PO does not process SDRs without decisions as appeals, it eliminates the participant's right to participate fully in all decisions related to his or her treatment.

Recommendation: The PO's compliance and oversight program should ensure that their internal monitoring, training, and internal audit processes are aligned with contractual requirements and are established to proactively identify potential deficiencies, implement corrective actions, and maintain compliance. The PO's compliance and oversight program policies and procedures should be reviewed and updated for effectiveness.

The PO should develop and Implement policies and procedures to ensure that SDRs with no decision are processed as an adverse benefit determination initiating an automatic appeals process. The PO must establish training protocols and ensure relevant personnel, including IDT, receive trainings on the policies and procedures including protocols for handling untimely notice of resolutions and the rights afforded to participants in such instances.

COMPLIANCE AUDIT FINDINGS

Medication and Supplement Disbursement

1. Clinical Rationale

The PO must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards. If a service recommended by an employee or contractor of the PO, including a specialist, is not approved or provided, the reasons for not approving or providing that service must be included in the participant's medical record. *(CFR, Title 42, section 460.210(b)(5); Contract, Exhibit A, Attachment 1 A1, Definitions, Pace Organization; PACE Program Agreement Number H6079, Article V, Requirements of Laws and Regulation)*

If the IDT determines that certain services are not necessary to the care of a participant, the reasoning behind this determination must be documented in the plan of care. All assessment and reassessment information must be documented in the participant's medical record. *(CFR, Title 42, section 460.104 (b)(1) & (f); Contract, Exhibit A, Attachment 10 A1, Provision 3& Attachment 1 A1, Definitions, Pace Organization; PACE Program Agreement Number H6079, Article V, Requirements of Laws and Regulation)*

The PO's policy, *Medical Records* (effective June 2023), states that if a service recommended by an employee or contractor of the PO, including a specialist, is not approved or provided, at a minimum the medical record must contain the reasons for not approving or providing that service.

Finding: The PO did not clearly document the reasons for not approving or providing services as recommended by the participant's provider.

The focused review team conducted three verification studies (orders, pharmacy PAs, and SDRs) for UM, each involved the review of participant's medical records. A total of 34 participant medical records were reviewed, which found the following:

- 2 of 34 samples where a participant's specialist made requests to change medication dosages. However, the change in dosage was denied and the reason for denial is not documented.
- 6 of 34 samples where a pharmacist made recommendations to either prescribe or discontinue medications for the participant and the

recommendation is denied, delayed, or ignored. The reason for denying, delaying, or ignoring the recommendations are not documented.

In a written response, the PO stated that all services require a PA or approval by the IDT before receipt, excluding emergency care. The PO also stated that if a specialist's recommendation is determined by the participant's PCP to be inappropriate, the recommendation will not be implemented, and the clinical rationale will be documented in the participant's medical record. However, the PO did not document clinical rationale for denying, delaying, or ignoring requests regarding a participant's medication.

In an interview and a follow-up written response, the PO stated that if a service is recommended by a provider or contracted specialist and is not implemented, the PO considers that to be a declined service. Meanwhile, if a service request undergoes the PA process and is not approved, the PO considers that to be a denied service. As a result, recommendations and requests made by contracted providers, per the PO, are not subject to the same level of scrutiny and tracking that is typical of PAs. Given that the PO lacked a tracking process, the PO was unable to provide a list of approved, modified, or denied PAs. Instead, the PO has an informal review system for provider recommendations as the default mechanism by which participants rely upon to receive medically necessary services.

When there is an informal review of provider recommendations, it eliminates the means in which a participant or provider can appeal IDT decisions. This informal review further fosters the underutilization of health care services. Lastly, if reasons for medical decisions are not clearly documented, it is difficult to ensure that appropriate guidelines and criteria are being adhered to or that clinical rationale for decisions are correct. This can lead to poor decision making, substandard care, and ultimately, patient harm.

Recommendation: The PO's compliance and oversight program should ensure that their internal monitoring, training, and internal audit processes are aligned with contractual requirements and are established to proactively identify potential deficiencies, implement corrective actions, and maintain compliance. The PO's compliance and oversight program policies and procedures should be reviewed and updated for effectiveness.

The PO should implement system changes to document PA decisions and reasons in participant medical records. The PO should update policies and procedures to ensure that documentation is complete and captures the reasons for not approving the service. The PO must establish training protocols and ensure relevant personnel, including IDT, and contracted providers receive trainings on the systems and policies and procedures.

2. Services Denied by Unqualified Health Professionals

The PO shall ensure that its PA, concurrent review, and retrospective review procedures includes qualified health care professionals who supervise review decisions, including service reductions, and a qualified physician reviews all denials that are made, in whole or in part, on the basis of medical necessity. *(Contract, Exhibit A, Attachment 5 A1, Provision 2(B))*

If a decision is delayed beyond time limits, the decision is considered a denial and must be immediately processed as such. *(Contract, Exhibit A, Attachment 5 A1, Provision 3(F))*

Finding: The PO made service denials that did not include review by a qualified physician.

The focused review team conducted three verification studies (orders, pharmacy PAs, and SDRs) for UM, each involved the review of participant's medical records. A total of 34 participant medical records were reviewed, which found the following:

- A participant's specialist recommended an increase in Buspirone for a participant, which was subsequently denied by a nurse practitioner. The denial by the nurse practitioner was not reviewed by a qualified physician. In addition, the participant's medical record also revealed that changes to their other medications (Lunesta, Ambien, and Duloxetine) were also denied by the nurse practitioner without review by a qualified physician.
- Four additional samples revealed that recommendations by a pharmacist were also denied by a nurse practitioner without review by a qualified physician.

In an interview and written response, the PO stated that service denials can be made by a nurse practitioner who can independently act in the capacity of an IDT primary care physician (PCP). This is because the PO's nurse practitioners and physicians occupy the same role in clinical care within the IDT. However, this is contrary to the contract requirement.

Service denials must be reviewed by a qualified health professional to ensure they are based on medical necessity. If participants are denied services that are medically necessary, it may result in adverse health outcomes.

Recommendation: The PO's compliance and oversight program should ensure that their internal monitoring, training, and internal audit processes are aligned with contractual requirements and are established to proactively identify potential deficiencies, implement corrective actions, and maintain compliance. The PO's

compliance and oversight program policies and procedures should be reviewed and updated for effectiveness. Ensuring service denials are overseen by qualified personnel is fundamental to PACE operations.

The PO should develop policies and procedures to ensure service denials are reviewed by a qualified physician. The PO must establish training protocols and ensure relevant personnel, including IDT, and contracted providers receive trainings. The PO should conduct internal audits of service requests and denials to ensure adherence updated policies and procedures.