DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

MEDICARE PARTS C AND D OVERSIGHT AND ENFORCEMENT GROUP

December 20, 2017

Ms. Sally Hartman
Senior Vice President
Riverside Health System
701 Town Center Drive, Suite 1000
Newport News, VA 23606

RE: Notice of Imposition of Sanctions to Suspend Enrollment of PACE Participants into Contract Number: H8655

Delivered by electronic mail to sally.hartman@rivhs.com

Dear Ms. Hartman:

Pursuant to the authority of sections 1894(e)(6)(B) and 1934(e)(6)(B) of the Social Security Act (the Act) and 42 C.F.R. §§ 460.40(a) and 460.42(a), the Centers for Medicare & Medicaid Services (CMS) hereby notifies Riverside Retirement Services, Inc. (Riverside) that CMS and the State Administrating Agency of Virginia, Virginia Department of Medical Assistance Services (VA DMAS) have made a determination to immediately suspend Riverside's ability to enroll new participants under its contract, number H8655, to provide services under the Programs of All-Inclusive Care for the Elderly (PACE) in Richmond and Newport News, VA. Riverside must immediately cease all marketing and enrollment activities by December 21, 2017.

CMS and VA DMAS have concluded that Riverside failed substantially to provide its participants with medically necessary items and services that are covered PACE services, which adversely affected (or had the substantial likelihood of adversely affecting) its participants. This determination was made as a result of significant clinical and operational deficiencies uncovered during a September 2017 audit. Consequently, CMS and VA DMAS have determined that Riverside's infrastructure cannot fully support the absorption of additional enrollees.

The enrollment sanction will remain in effect until CMS and VA DMAS are satisfied that the deficiencies upon which the determination was based have been corrected and are not likely to recur. The enrollment suspension will apply to all potential participants, including Medicare-only and dual eligible beneficiaries. VA DMAS will be responsible for suspending enrollment of Medicaid-only beneficiaries.

PACE Program

The PACE program provides comprehensive medical and social services to certain frail, community-dwelling elderly individuals, most of whom are dually eligible for Medicare and Medicaid benefits. An interdisciplinary team of health professionals provides PACE participants with coordinated care. For most participants, the comprehensive service package enables them to remain in the community rather than receive care in a nursing home. Financing for the program is capped, which allows providers to deliver all services participants need rather than only those reimbursable under Medicare and Medicaid fee-for-service plans. PACE is a program under Medicare, and states can elect to provide PACE services to Medicaid beneficiaries as an optional Medicaid benefit. The PACE program becomes the sole source of Medicaid and Medicare benefits for PACE participants.

PACE organizations (POs) are entities that have in effect a PACE program agreement with CMS and the State administering agency (SAA) to operate a PACE program. Individuals can join PACE if they meet certain eligibility requirements, including that they must:

- Be age 55 or older;
- Live in the service area of a PO;
- Be determined by the SAA to need the level of care required under the state Medicaid plan for coverage of nursing facility services; and
- At the time of enrollment, be able to live safely in a community setting.

Summary of Noncompliance

From September 11th through 15th, 2017, CMS conducted an audit of Riverside's operations as a PO. During the audit, CMS and state auditors found substantial non-compliance with PACE regulations regarding clinical appropriateness and care planning; service delivery requests, appeals, and grievances; and personnel qualifications.

Basis for Enrollment Sanction

CMS, in consultation with VA DMAS, has determined that Riverside's violations provide a sufficient basis for the imposition of contract sanctions under 42 C.F.R. § 460.42(a). Specifically, Riverside:

- Failed substantially to provide participants with medically necessary items and services that are covered PACE services, which adversely affected (or had the substantial likelihood of adversely affecting) participants (42 C.F.R. § 460.40(a)).

The violations upon which this determination was based are as follows:

1. Failure to provide services that were adequate and/or accessible to meet the needs of its participants. As a result, participants experienced delays and/or denials of medically necessary items, services, and interventions, which exacerbated (or had the potential to exacerbate) their health conditions. This is in violation of 42 C.F.R. § 460.98(d)(2) and IOM Pub. 100-11, PACE Manual, Chapter 6, Section 50.

Case Examples: Auditors identified 7 participants who did not receive required services while home bound, resulting in three negative outcomes among three participants. One participant experienced a decline in the activities of daily living (ADL). Another experienced multiple falls, while a third experienced three falls and a delay in counseling.

Auditors also identified 46 participants for whom there was no documentation that they received one or more medications at the PACE center. Among this group, 445 medications were undocumented or missed doses, resulting in at least one participant experiencing low phenytoin levels on three occasions.

The PO failed to provide 36 participants with prescribed medications; and 10 of those participants experienced delays in receiving medications of 7 days or more. This conduct resulted in hospitalization of 2 participants.

Auditors identified 37 participants who did not receive primary care physician/nurse practitioner-ordered services for 30 or more days. The services included wound care, a ramp for a participant's home, physical therapy, occupational therapy, brake extenders, mattresses, rollators, a quad cane, hospital beds, a wheel chair, dental consultations, an ophthalmology consultation, weekly weights, an international normalized ration (INR), and a urology consultation. One affected participant experienced a functional loss and a progression in wounds.

2. Failure to ensure that the interdisciplinary team (IDT) remained alert to pertinent input from other team members, participants, and caregivers. As a result, participants experienced delays and/or denials of medically necessary items, services and interventions, which exacerbated (or had the potential of exacerbating) existing medical conditions. This is in violation of 42 C.F.R. § 460.102(d)(2)(ii).

Case Examples: Auditors identified 37 participants who did not receive primary care physician/nurse practitioner-ordered services for 30 or more days. The services included wound care, a ramp for the participant's home, physical therapy, occupational therapy, brake extenders, mattresses, rollators, a quad cane, hospital beds, a wheel chair, dental consultations, an ophthalmology consultation, weekly weights, an international normalized ration (INR), and a urology consultation. One affected participant experienced a functional loss and a progression in wounds.

3. Failure to develop a comprehensive plan of care promptly following enrollment. As a result, participants experienced delays and/or denials of medically necessary items, services and interventions, which exacerbated (or had the potential of exacerbating) existing medical conditions. This is in violation of 42 C.F.R. § 460.106(a)-(b).

Case Examples: Auditors found 21 participants with initial care plans with missing problems (i.e., potential or current medical, functional, or psychosocial issues that must be managed by multiple disciplines), interventions, and goals that Riverside determined should have been included.

4. Failure to conduct in-person reassessments as required. As a result, participants experienced delays and/or denials of medically necessary items and services, which may have contributed to declining health. This is in violation of 42 C.F.R. §§ 460.104(d)(1) and (2).

Case Examples: POs must conduct an in-person reassessment of a participant in the event of a change in the participant's status or at the request of a participant or designated representative. Auditors identified 133 participants who did not have reassessments completed following a change in the participant's condition, resulting in one participant experiencing functional loss and a progression in wounds. Auditors also determined that Riverside did not conduct in-person reassessments following service requests in 214 out of 335 instances. Of the 214 service requests for which there was no corresponding reassessment, 44 were denied and 170 were approved.

5. Failure to provide care and services in accordance with participants' approved care plans. As a result, participants experienced delays and/or denials of medically necessary items, services and interventions, which exacerbated (or had the potential of exacerbating) existing medical conditions. This is in violation of 42 C.F.R. § 460.106(c).

Case Examples: Auditors found that 5 participants did not receive care plan-directed services during the audit review period.

6. Failure to ensure that care plans included the required content. As a result, participants experienced delays and/or denials of medically necessary items, services and interventions, which exacerbated (or had the potential of exacerbating) existing medical conditions. This is in violation of 42 C.F.R. § 460.106(b).

Case Examples: Auditors found that 262 participants' plans of care that followed annual, semiannual, and unscheduled reassessments were missing problems, interventions, and goals that Riverside determined should have been included. Riverside identified 3 participants who experienced negative outcomes as a result of these omissions. One participant had a bed bug infestation and did not receive required services as identified by the IDT while restricted to the home, resulting in a decline in functional status. A second participant experienced a fall, while a third experienced falls, failed to attend scheduled counseling, and experienced a decline in functional status.

Other Violations Found During the Audit

In addition, CMS and state auditors discovered other violations that indirectly impact the quality of care provided to participants. Although these secondary violations do not form the basis for the enrollment sanction, their correction, in many cases, would be necessary in order for this PO to ensure the appropriate care for its participants as they are closely related to the clinical and service delivery violations described in detail above.

Personnel

- Riverside failed to provide OSHA training as required.
- Riverside failed to provide emergency training as required.

- Riverside failed to provide adequate training to personnel and contractors with respect to their specific duties.
- Riverside failed to evaluate the competency of all personnel and contractors prior to those individuals performing participant care.
- Riverside failed to verify that all personnel and contractors were not excluded from participation in the Medicare and Medicaid programs.
- Riverside failed to verify that all personnel and contractors have not been convicted of physical, sexual, drug, or alcohol abuse.
- Riverside failed to ensure that all personnel and contractors who have direct participant contact are free from communicable diseases before performing participant care.
- Riverside failed to ensure that all personnel and contractors who have direct participant contact have all immunizations up-to-date before performing participant care.

Service Delivery Requests, Appeals and Grievances (SDAG)

- Riverside failed to properly resolve all issues in participants' grievances.
- Riverside inappropriately extended the timeframe for a service delivery request.
- Riverside's denial notifications failed to include the specific reason(s) for the denial in a clear and understandable manner.
- Riverside's denial notifications did not include the participant's right to appeal the denial and/or information about how to appeal the denial.
- Riverside did not automatically process an appeal following an untimely decision for a service.
- Riverside failed to notify participants of the standard appeal decision within 30 days of receiving the appeal or sooner if the participant's health condition requires.
- Riverside failed to provide participants a reasonable opportunity to present evidence during their appeal.
- Riverside failed to appropriately notify CMS, the SAA, and/or the participant of adverse appeal decisions.
- Riverside failed to recognize complaints as grievances.
- Riverside failed to appropriately categorize and document service delivery requests.
- Riverside failed to ensure the full IDT was involved in the review of service delivery requests.

Clinical Appropriateness and Care Planning

- Riverside failed to ensure that all personnel and contracted staff who have direct participant contact only act within the scope of their authority to practice.

Opportunity to Correct

Pursuant to 42 C.F.R. § 460.42(c), the enrollment suspension will remain in effect until CMS is satisfied that Riverside has corrected the violations which form the basis for the sanction and that the violations are not likely to recur. Riverside is solely responsible for the development and implementation of its Corrective Action Plan (CAP), and for demonstrating to CMS and VA DMAS that the underlying deficiencies have been corrected and are not likely to recur. Riverside will need to submit a CAP to CMS that covers all violations, which form the basis for the sanction within seven (7) calendar days from the date of receipt of this notice, or by

December 28, 2017. If Riverside needs additional time beyond seven (7) days to submit its CAP, please contact your enforcement lead.

Once Riverside has fully implemented its CAP and believes these violations have been corrected, it must submit to CMS an attestation from Riverside's Chief Executive Officer, or most senior official, stating that Riverside has corrected the deficiencies that are the basis for the sanction and that they are not likely to recur.

Validation Audit

Riverside will be required to undergo a validation audit of all the operational areas cited in this notice before the enrollment suspension will be lifted. Upon completion of the validation audit, CMS and VA DMAS will make a determination about whether the deficiencies that are the basis for the sanctions have been corrected and are not likely to recur.

Opportunity to Respond to Notice

Riverside may respond to this notice in accordance with the procedures specified in 42 C.F.R. § 422.756(a)(2). Riverside has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by January 2, 2018. Please note that CMS considers receipt as the day after the notice is sent by fax, email, or overnight mail or in this case, December 21, 2017. If you choose to submit a rebuttal, please send it to the attention of Kevin Stansbury at the address noted below. Note that the sanctions imposed pursuant to this letter are not stayed pending a rebuttal submission.

Right to Request a Hearing

Riverside may request a hearing to appeal CMS's determination in accordance with the procedures outline in 42 C.F.R. Part 422, subpart N (§§ 422.641 – 422.696). Pursuant to 42 C.F.R. § 422.662, a written request for a hearing must be received by CMS within fifteen (15) calendar days of receipt of this notice, or by January 5, 2018. Please note, however, a request for a hearing will not delay the date specified by CMS as to when the sanction becomes effective. Your hearing will be considered officially filed on the date that it is mailed; accordingly, we recommend using an overnight traceable mail carrier.

The request for a hearing must be sent to the CMS Hearing Office at the following address:

Benjamin Cohen
CMS Hearing Officer
Office of Hearings
ATTN: HEARING REQUEST
Centers for Medicare & Medicaid Services
1508 Woodlawn Drive
Suite 100
Mail Stop WD-02-15
Baltimore, MD 21244-2670
Phone: 410-786-3169

Email: Benjamin.Cohen@cms.hhs.gov

A copy of the hearing request should be also be sent to CMS at the following address:

Kevin Stansbury
Acting Director, Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Mail Stop C1-23-17
Email: Kevin.Stansbury@cms.hhs.gov

CMS will consider the date the Office of Hearings receives the email or the date it receives the fax or traceable mail document, whichever is earlier, as the date of receipt of the request. The request for a hearing must include the name, fax number, and email address of the contact within Riverside (or an attorney who has a letter of authorization to represent the organization) with whom CMS should communicate regarding the hearing request.

If you have any questions about this notice, please call or email the enforcement contact provided in your email notification.

Sincerely,

/s/

Vikki Ahern
Director
Medicare Parts C and D Oversight and Enforcement Group

cc:

Tammy McCloy, CMS/CMHPO/Region III
Annmarie Anderson, CMS/CMHPO/Region III
Judith Geisler, CMS/CM/MOEG
Kevin Stansbury, CMS/CM/MOEG/DCE
Terry Smith, VA DMAS
Steve Ankiel, VA DMAS