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

October 3, 2017

Mr. Hogan Coble
Executive Director
Via Christi Healthcare Outreach for Elders, Inc.
2622 W. Central, Suite 101
Wichita, KS 67203

Re: Notice of Imposition of Sanctions to Suspend Enrollment of PACE participants into contract number: H1714

Dear Mr. Coble:

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 Via Christi Healthcare Outreach for Elders, Inc., d/b/a Via Christi HOPE (VCH), that CMS and the State Administering Agency of Kansas, the Kansas Department of Aging and Disability Services (KDADS), have made a determination to immediately suspend VCH's ability to enroll new participants into PACE contract number H1714 operating in Wichita, KS. VCH must immediately cease all marketing and enrollment activities by October 4, 2017.

CMS and KDADS have concluded that VCH 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 severe clinical and operational deficiencies uncovered during an August 2017 unscheduled audit. Consequently, CMS and KDADS have determined that VCH's infrastructure cannot fully support the absorption of additional enrollees.

The enrollment sanction will remain in effect until CMS and KDADS 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. KDADS will be responsible for restricting enrollment of Medicaid-only beneficiaries.

PACE Program

The Programs of All-Inclusive Care for the Elderly (PACE) 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 August 7, 2017 to August 11, 2017, CMS and KDADS conducted an unscheduled audit of VCH's operations as a PO. During the audit, CMS and state auditors found substantial noncompliance with PACE regulations regarding clinical appropriateness and care planning; service delivery requests, appeals and grievances; and quality assurance. The violations described below, which form the primary basis for this enforcement action, resulted in participants experiencing delays and/or denials of medically necessary items and services and inadequate management of their medical conditions.

Serious Clinical Appropriateness and Care Planning, Service Delivery, and Appeals and Grievance Violations

Auditors identified many examples where VCH failed 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.

First, VCH failed to timely schedule orders for specialty services in number of cases sampled during the audit, indicating a widespread failure to provide medically necessary items and services. For example, in March 2017, a newly enrolled, homebound participant was assessed as having broken teeth and needing a dental appointment (*See* Exhibit A, pages 3-4). Two months

later, in May 2017, the participant was hospitalized due to a tooth abscess. In that two month period, VCH did not arrange for the participant to see a dentist. At the time of the audit in August 2017, the participant was breathing through a ventilator because his tooth infection became septic and caused respiratory failure (*See* Exhibit A, pages 8-11). The audit revealed other case failures involving different medical circumstances. Additionally, shortly after the audit, VCH self-identified another instance in which a participant did not receive timely dental services. VCH did not arrange for this participant to get dentures until almost a year after her teeth were assessed as un-restorable.

Second, VCH failed to conduct timely assessments of emerging and/or escalating medical conditions for participants who repeatedly requested medical intervention. For example, a participant with an intellectual disability, who also suffers from diabetes and peripheral vascular disease (PVD), had sustained a foot injury in January 2017. The following day, the participant was seen by a nurse and student nurse who wrapped her foot and determined that it was not broken (*See* Exhibit A, pages 13-16). Over the course of the next two weeks, the participant telephoned VCH on numerous occasions complaining of severe foot pain. The on-call nurses advised the participant on how to manage the pain and reassured her that her foot was not broken and that it would heal (*See* Exhibit A, pages 17-21). In late February 2017, the participant came into the PACE center after having pierced her foot to drain the build-up of fluid. She was seen onsite that day by a primary care physician (PCP) who suspected that she had sustained a vascular injury (*See* Exhibit A, pages 22-26). Her foot was amputated in March 2017 due to complete occlusion (*See* Exhibit A, 27-29).

Additionally, the participant mentioned above with the tooth abscess had telephoned VCH's on-call nurses several times complaining of severe tooth and mouth pain in the four days leading up to his admission to the Emergency Room (ER). A nurse did not come to the participant's home to conduct an assessment until May 16, 2017, at which time she determined that the participant needed to go to the ER (*See* Exhibit A, pages 5-7).

Auditors discovered that VCH also failed to provide immediate access to emergency care. PACE participants residing in assisted living facilities and nursing homes are at risk of not receiving cardiopulmonary resuscitation (CPR), or other life saving measures, in the event of a medical emergency due to a PO's failure to collect and maintain current code statuses and advance directives, and to distribute that information to both internal and contracted providers. For example, a VCH participant who was found not breathing did not receive CPR for approximately 24 minutes due to significant internal confusion regarding her code status. CPR in that instance was unsuccessful (*See* Exhibit B, pages 31-33). VCH also failed, generally, to establish a protocol to handle emergency situations that arise outside of the facility, which could impede access to emergency care. This is in violation of 42 C.F.R. § 460.100(b)(1)–(2) and IOM Pub. 100–11, PACE Manual, Chapter 6, Section 30.

In addition, VCH failed to provide care and services in accordance with participants' approved plans of care which delayed and/or denied medically necessary items and services to participants, and which also may have contributed to their health conditions declining. This is in violation of 42 C.F.R. § 460.106(c). Auditors identified many examples of this violation. Specifically, VCH failed to provide the full extent of approved home health services. For example, VCH home

health aides would fail to show-up to participants' homes when scheduled or would arrive on the wrong days/times. Aides would often not perform the chores and/or meal preparation services specified in the approved plans of care. VCH would resolve these grievances on an individual basis by reassigning another home health aide to the aggrieved participant. However, participants continued to complain about this issue and, at the time of the audit, VCH still had not developed or implemented a plan to correct this ongoing issue.

VCH also failed to furnish approved services included in revised plans of care as expeditiously as the participants' health condition required in violation of 42 C.F.R. § 460.104(e). Auditors identified several examples of this violation indicating a systemic failure to provide approved services in a timely manner, if at all. In one case, the PO did not effectuate an approved service request for Hepatitis C medication for over a year and a half. The participant first requested Hepatitis C drug therapy in January 2016. That request was denied by VCH in August 2016. In October 2016, the participant filed a grievance in which VCH agreed to schedule a consultation with a gastroenterologist (GI). The GI consultation was not performed until March 2017. The GI recommended that the participant begin Hepatitis C treatment. However, as of August 2017, the participant still had not received his medication (*See* Exhibit C, pages 35-42).

Additionally, VCH failed to furnish approved wheelchair ramps and walkers for several participants identified as fall risks. In one case, VCH waited six months to install a wheelchair ramp after approval. In another instance, VCH never provided the wheelchair ramp because the participant had moved to a higher level of care facility, albeit six months after the approval. For another participant, a walker was approved but never provided (*See* Exhibit C, page 42). VCH also did not provide increased incontinence supplies pursuant to an appeal decision in favor of a participant, for nearly 6 months.

The auditors also discovered that VCH's PCP failed to manage a participant's medical situation, in violation of 42 C.F.R. § 460.102(c). This led to a PACE participant receiving inadequate oversight of her medical condition which led to a misdiagnosis and subsequent hospitalization. Auditors found one particularly disturbing example of a PCP mismanaging a participant's medical condition. Here, an advanced practice nurse (APRN) employed by VCH, attributed a participant's thirty-nine pound weight gain over the course of thirty days to excessive caloric intake and inactivity. In other words, the APRN determined the extra weight was pure fat. This participant suffered from congestive heart failure (CHF) and obesity. After the diagnosis, the participant made several calls to VCH complaining that her clothes were wet because she was "leaking." However, VCH's on-call nurses reassured her that the weight gain was solid fat. Those concerns were reported to the PCP with no intervention (*See* Exhibit D, pages 44-47). Four days later, the participant was admitted to the ER with a weeping edema. As it turns out, the weight gain was actually fluid and not fat (*See* Exhibit D, pages 48-51). That APRN was later transferred to another Ascension-owned facility in Wichita, KS.

Auditors found numerous examples indicating a systemic failure to conduct in-person participant assessments and reassessments as often as required. This is in violation of 42 C.F.R. §§ 460.104(a), 460.104(c), and 460.104(d)(1)–(2). First, VCH regularly denied requests for services without performing an in-person assessment. For example, on several occasions, VCH denied requests for increased PACE center day attendance without conducting an assessment. In

another case, VCH denied a request for extra oxygen tanks without conducting an in-person assessment. VCH also denied a request for a personal emergency system without conducting an in-person assessment.

Second, VCH failed to conduct unscheduled reassessments in response to significant changes in participants' health and/or psychosocial status. For example, one participant was hospitalized for renal failure and placed on dialysis. Upon discharge, VCH placed her in a higher level of care facility but did not conduct a proper reassessment of the participant. Auditors noted numerous other instances of participants presenting at the hospital with serious ailments in which no reassessments were conducted afterwards.

In another case, a participant with diabetes had been without electricity for a prolonged period of time which prevented him from keeping his insulin at the required temperature during the hot summer months. At the time of the audit, VCH had not conducted a reassessment to determine if it was safe for this participant to continue living at home. In another example, the PO failed to conduct an annual reassessment of a participant because he would not come to the PACE center.

Finally, auditors cited VCH for failing to appropriately categorize and document service requests and appeals in violation of 42 C.F.R. § 460.122. As a result, participants likely experienced delays and/or denials of medically necessary items and services because the PO did not resolve service delivery requests and appeals through the appropriate procedures. Auditors identified three examples of this violation during the audit. First, VCH misclassified an appeal for increased PACE center days as a service delivery request, denying the participant his right to an impartial second-level review. Second, VCH misclassified a service delivery request for coverage of an over-the-counter drug as a grievance, delaying the participant's receipt of a determination and ability to appeal an adverse decision. Lastly, VCH misclassified a participant's appeal for Hepatitis C treatment as a grievance, delaying access to life-saving medication.

Other PACE Program Violations

In addition to the most egregious findings, CMS and state auditors discovered other violations that indirectly impact the quality of care delivered 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 that newly enrolled participants are appropriately cared for, as these violations are closely related to the clinical and service delivery violations described in detail above. These audit findings include:

- VCH failed to furnish comprehensive medical, health, and social services that integrate acute and long-term care at the PACE center, participant's home, and inpatient facilities.
- VCH failed to ensure that the Interdisciplinary Team (IDT) remained alert to pertinent input from other team members, participants, and caregivers.
- VCH failed to maintain a medical record for each participant that was complete, accurate, and available to all staff.
- VCH failed to analyze any incidents of infection to identify trends and to develop corrective actions related to the reduction of future incidents.

- VCH failed to ensure that the data used for outcome monitoring was accurate or complete.
- VCH failed to immediately correct any identified problem that directly or potentially threatens the health and safety of the PACE participants.
- VCH did not ensure that all IDT members, PACE staff, and contract providers were involved in the development and implementation of quality assessment and performance improvement activities.
- VCH failed to maintain, aggregate, and analyze information on appeal proceedings and use this information in the organization's internal quality assessment and performance improvement program.
- VCH failed to ensure its Medical Director was appropriately involved in the oversight of the quality assessment and performance improvement program related to participant care and clinical outcomes.
- VCH failed to appropriately categorize and document appeals.
- VCH inappropriately extended the timeframe for service delivery requests.
- VCH failed to notify participants or their representatives of its decision to approve or deny a request for reassessment within 72 hours from the date of receipt of a request by the IDT, or within 8 days if an extension was taken.
- VCH failed to provide oral notification to participants when denying service delivery requests
- VCH's written denial notifications of service delivery requests did not include the participant's right to appeal and/or information about how to appeal the denial.
- VCH did not automatically process an appeal following an untimely decision for a service.
- VCH failed to ensure appeals were reviewed by an appropriately credentialed and impartial third party.
- VCH failed to resolve and/or notify participants and/or their caregivers of the resolution of their grievances in a timely manner.
- VCH failed to follow Centers for Disease Control and Prevention (CDC) standard precautions when providing care.

Basis for Enrollment Sanction

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

- 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.

2. Failure to provide immediate access to emergency care. As a result, participants were likely delayed and/or denied access to emergency care. This is in violation of 42 C.F.R. § 460.100(b)(1)–(2) and IOM Pub. 100–11, PACE Manual, Chapter 6, Section 30.

3. 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 and services, which may have contributed to their health conditions declining. This is in violation of 42 C.F.R. § 460.106(c).

4. Failure to furnish approved services as expeditiously as the participant's health condition required. As a result, participants experienced delays and/or denials of medically necessary items and services, which may have contributed to their health conditions worsening. This is in violation of 42 C.F.R. §§ 460.104(e)–(d).

5. Failure of the PCP to manage a participant's medical situation. A participant received inadequate management of her medical conditions, which exacerbated (or had the potential to exacerbate) her health conditions. This is in violation of 42 C.F.R. § 460.102(c).

6. Failure to conduct-in person assessments and reassessments as often as required. As a result, participants likely experienced delays and/or denials of medically necessary items, services, and interventions, which may have contributed to their health conditions worsening. This is in violation of 42 C.F.R. §§ 460.104(a), 460.104(c), and 460.104(d)(1)–(2).

7. Failure to appropriately categorize and document service requests and appeals. As a result, participants likely experienced delay and/or denials of medically necessary items and services because the PO did not resolve service delivery requests and appeals through the appropriate procedures. This is in violation of 42 C.F.R. § 460.122

The nature of VCH's substantial noncompliance supports the immediate suspension of VCH's ability to enroll new participants into its PACE program agreement. Consequently, these sanctions are effective on October 4, 2017.

Opportunity to Correct

Pursuant to 42 C.F.R. § 460.42(c), the enrollment suspension will remain in effect until CMS and KDADS are satisfied that VCH has corrected the violations which form the basis for the sanction and that the violations are not likely to recur. VCH is solely responsible for the development and implementation of its Corrective Action Plan (CAP), and for demonstrating to CMS and KDADS that the underlying deficiencies have been corrected and are not likely to recur. VCH 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 October 11, 2017. If VCH

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

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

Validation Audit

VCH 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 KDADS will make a determination about whether the deficiencies that are the basis for the sanctions have been corrected and are not likely recur.

Opportunity to Respond to Notice

VCH may respond to this notice in accordance with the procedures specified in 42 C.F.R. § 422.756(a)(2). VCH has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by October 16, 2017.[1] Please note that CMS considers receipt as the day after the notice is sent by fax, email, or overnight mail or in this case October 4, 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

VCH may request a hearing to appeal CMS's determination in accordance with the procedures outlined 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 October 19, 2017. 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 request 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

[1] If the 10th day falls on a weekend or federal holiday, you have until the next regular business day to submit your request.

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 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 e-mail address of the contact within VCH (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

Attachments

Exhibit A – Medical Records Supporting Violation of 42 C.F.R. § 460.98(d)(2) and IOM Pub. 100-11, PACE Manual, Chapter 6, Section 50
Exhibit B – Medical Records Supporting Violation of 42 C.F.R. § 460.100(b)(1)–(2) and IOM Pub. 100-11, PACE Manual, Chapter 6, Section 30
Exhibit C – Medical Records Supporting Violation of 42 C.F.R. § 460.104(e)
Exhibit D – Medical Records Supporting Violation of 42 C.F.R. § 460.102(c)

cc: Peter Leibold, Ascension Health
Judith Flynn, CMS/CMHPO/Region VII

Dale Ferguson, CMS/CMHPO/Region VII
Amy Flynn, CMS/CMHPO/Region VII
Delorse Mays, CMS/CMHPO/Region VII
Judith Geisler, CMS/CM/MOEG
Kevin Stansbury, CMS/CM/MOEG/DCE
Kathryn Coleman, CMS/CM/MCAG
Amy Penrod, KDADS
Cindy Wichman, KDADS/HCBS
Carrie Proffitt, KDADS/HCBS