

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



**MEDICARE PARTS C & D OVERSIGHT AND ENFORCEMENT GROUP**

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August 1, 2013

**VIA:**

**EMAIL** ([cpope@lubbockmhm.org](mailto:cpope@lubbockmhm.org))

**AND FACSIMILE** (806-766-0250)

Ms. Cathy Pope  
Chief Executive Officer  
Silver Star Health Network  
P.O. Box 2828  
Lubbock, TX 79408  
Phone: 806-766-0221

Re: Notice of Imposition of Civil Money Penalty for Program of All-inclusive Care for the Elderly (PACE) Silver Star Health Network (H9998)

Dear Ms. Pope:

Pursuant to 42 C.F.R. §§ 460.40(a) and 460.46(a)(4), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Silver Star Health Network (Silver Star), that CMS has made a determination to impose a civil money penalty (CMP) in the amount of \$25,000 for PACE contract number H9998.

CMS has determined that Silver Star failed substantially to provide its participants with medically necessary items and services that are PACE covered services and such failure has adversely affected (or had the substantial likelihood of adversely affecting) the participants.

**Summary of Noncompliance**

CMS conducted a total of five (5) monitoring visits/audits from December 2010 through April 2013. These audits were conducted to determine if Silver Star is in compliance with PACE regulations and guidelines.

CMS determined that Silver Star failed to implement an adequate infection control plan, failed to ensure a safe and sanitary environment, failed to have required and properly trained personnel, and failed to properly document information in medical records. Silver Star's failures violate CMS requirements contained at §§ 1894, 1934 and of the Social Security Act; 42 C.F.R. Part 460,130 Subparts E, F, and L.

## **PACE Program Background and Relevant Requirements**

*42 C.F.R. § 460; Internet Only Manual (IOM) Pub.100-11 Programs of All-Inclusive Care for the Elderly (PACE) Manual.*

PACE is a Medicare and Medicaid program that helps people meet their health care needs in the community instead of going to a nursing home or other care facility. It provides comprehensive long term services and support to Medicaid and Medicare enrollees. A team of health professionals provides individuals with coordinated care. For most participants, the comprehensive service package enables them to receive care at home rather than receive care in a nursing home.

PACE programs are designed to provide a range of integrated preventative, acute care, and long-term care services to manage the often complex medical, functional, and social needs of the frail elderly. Health care services are designed to meet the following objectives:

- 1) Enhance the quality of life and autonomy for frail, older adults;
- 2) Maximize dignity of, and respect for, older adults;
- 3) Enable frail, older adults to live in the community as long as medically and socially feasible; and
- 4) Preserve and support the older adult's family unit.

PACE organizations must provide all Medicare and Medicaid covered items and services as authorized by the interdisciplinary team, as well as additional medically necessary services not covered by Medicare or Medicaid to participants in all settings. PACE organizations must establish and implement a written plan to furnish care that meets the needs of each participant including medical, health and social services that integrate acute and long term care services. 42 C.F.R. §460.92 and 460.98(a) and (b).

PACE organizations are required to establish and maintain an interdisciplinary team to comprehensively assess and meet the individual needs of each participant. The interdisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of twenty-four (24) hour care delivery. 42 C.F.R. §460.102.

Each team member of the interdisciplinary team is responsible for the following:

- Regularly informing the interdisciplinary team of the medical, functional, and psychosocial condition of each participant;
- Remaining alert to pertinent input from other team members, participants, and caregivers; and
- Documenting changes of a participant's condition in the participant's medical record consistent with documentation policies established by the medical director.

A PACE organization must employ, or contract with, a medical director who is responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality improvement program. 42 C.F.R. §§ 460.60(c) and 460.70.

### **Deficiencies Related to Providing Medically Necessary Services to Participants**

CMS regulations provide a network of interrelated multidisciplinary requirements which are central to the provision of all medically necessary PACE covered services. CMS audits have identified multiple violations of PACE requirements which have caused Silver Star to fail in providing medically necessary PACE covered services, including:

- Failure to monitor or assess the medical needs of participants, in violation of 42 C.F.R. §§460.92, 460.98(a), 460.102(d) and (e), 460.104(a) and (c) through (e), 460.106 (c) through (f), and 460.210. For example, in cases where there was a clinical diagnosis of diabetes, dietary restrictions were not discussed and/or considered during Interdisciplinary Team meetings. Additionally, a participant failed to have a new patient assessment documented in the medical record following a surgery. This assessment is vital to document significant changes that could alter the participants' plan of care.
- Failure to maintain a single, comprehensive participant medical record in accordance with accepted professional standards in violation of 42 C.F.R. §§460.102(d)(2)(iii), 460.106(f) and 460.210. Audits found multiple instances where Silver Star failed to document significant health changes or events in participants' medical records. Specifically, in the case of a Clostridium Difficile (C. Diff) outbreak in December 2012 and January 2013, laboratory results and clinical care discussions pertaining to participants with symptoms of C. Diff or with a diagnosis of C. Diff were not recorded in medical records.
- Failure to maintain and adequately train required staff in violation of 42 C.F.R. §§ 460.60, 460.66 and 460.72. Silver Star's Medical Director resigned on October 27, 2012 and was not replaced with a part time Medical Director until April 2013; and the Clinic Nurse Manager resigned January 11, 2013 and was not replaced until April 2013. CMS and the Texas Department of Aging and Disability Services (DADS) have conducted nearly daily technical assistance calls with Silver Star in an effort to assist recently hired staff in correcting multiple long standing deficiencies.
- Failure to ensure a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services that protects the dignity and privacy of the participant in violation of 42 C.F.R. §460.72(a). During the most recent audit, several failures were identified including improperly labeled supplies of medications, improper storage and care of medications and medical supplies and expired medications included in supplies of available medications. All of these deficiencies have the potential to cause serious harm to participants during the course of treatment. Previous audits also found failures to monitor call lights, failure to ensure the emergency cart contained life-saving equipment, and the inappropriate storage of biohazard bags with oxygen equipment.

Silver Star has been notified by CMS three (3) times in less than two (2) years about deficiencies in the physical environment of its facility (December 2010, November 2011, and September 2012).

- Failure to implement an adequate plan to properly ensure that infections are controlled, and to take protections to limit exposure to infections in violation of 42 C.F.R. §460.74. These failures resulted in numerous PACE participants being exposed to a highly contagious, potentially deadly infection of Clostridium Difficile (C. Diff) in December 2012 and January 2013.

At the time of the outbreak, Silver Star was already on notice of deficiencies in their infection control plans and had significant opportunities to correct these serious problems. CMS first cited Silver Star during the December 2010 Technical Advisory Visit (TAV). During this visit CMS noted that Silver Star's log failed to record resolution of participant infections or if/when treatment plans for antibiotics had been changed or discontinued. CMS cited Silver Star again in November 2011 for their failure to implement an adequate infection control plan. Silver Star failed to show that they took any actions to reduce future incidents of infection. In fact, the clinical nurse and Center Director confirmed that the PACE organization lacked a plan to address newly developed infection trends or to reduce the spread of infections.

The December 2012 and January 2013 C.Diff outbreak demonstrated that Silver Star failed to ensure these deficiencies were corrected and not likely to recur as discussed during the September 2012 audit. During the audit the Infection Control Coordinator (ICC) acknowledged that Silver Star had not provided any instructions for the tracking and training of infections nor did the ICC even know the clinic nurse, who would be one of the people managing infections on a daily basis. During the audit, the Quality Assessment and Performance Improvement Plan (QAPI) coordinator confirmed that the organization did not have a functioning Infection Control Plan.

### **Basis for Civil Money Penalty**

Pursuant to 42 C.F.R. §§ 460.40(a) and 460.46(a)(4), CMS has determined that Silver Star's violations of CMS PACE requirements are significant enough to warrant the imposition of a CMP in the amount of \$15,000. Silver Star failed to provide medically necessary items and services and those failures adversely affected, or had the substantial likelihood of adversely affecting, PACE participants.

### **Right to Request a Hearing**

Silver Star may request a hearing to appeal CMS's determination in accordance with the procedures outlined in § 42 C.F.R. Part 422, Subpart T. Silver Star must send a written request for a hearing to the Departmental Appeals Board office listed below within 60 calendar days from receipt of this notice, or by October 1, 2013. 42 C.F.R. § 422.1020. The request for

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hearing must identify the specific issues and the findings of fact and conclusions of law with which Silver Star disagrees. Silver Star must also specify the basis for each contention that the finding or conclusion of law is incorrect. The request should be sent to:

Civil Remedies Division  
Department of Health and Human Services  
Departmental Appeals Board  
Medicare Appeals Council, MS 6132  
330 Independence Ave., S.W.  
Cohen Building Room G-644  
Washington, D.C. 20201

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

Patricia Axt, Director, Division of Compliance Enforcement  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
MAIL STOP: C1-22-06  
Baltimore, MD 21244  
Email: [Trish.Axt@cms.hhs.gov](mailto:Trish.Axt@cms.hhs.gov)  
FAX: 410-786-6301

If Silver Star does not request an appeal in the manner and timeframe described above, the initial determination by CMS to impose a CMP will become final and due on October 2, 2013. Silver Star may choose to have the penalty deducted from its monthly payment, transfer the funds electronically, or mail a check to CMS.

CMS considers these continued quality of care issues to provide medically necessary items and services to be extremely serious. We are closely monitoring your organization's operations to determine if additional action is warranted including the imposition of intermediate sanctions, other enforcement actions or contract termination as described in 42 C.F.R. Part 460, Subpart D.

If Silver Star has any questions about this notice, please call or email the enforcement contact provided in the email notification.

Sincerely,

/s/

Gerard J. Mulcahy  
Director  
Medicare Parts C&D Oversight and Enforcement Group

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cc: Ms. Julie Kennedy, Associate Regional Administrator, CMS/CMHPO/Region 6  
Ms. Lynne Clark, Account Manager, CMS/CMSHPO/Region 6  
Mr. Arthur Pagan, Branch Manager, CMS/CMHPO/Region 6