

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 ([bwhite@alexianbrothers.net](mailto:bwhite@alexianbrothers.net) )**  
**AND FACSIMILE (314-771-7830)**

Ms. Beverly White  
Interim Chief Executive Officer  
Alexian Brothers Community Services  
3900 S. Grand Blvd.  
St. Louis, MO 63118  
Phone: 314-771-5800 Ext 129

Re: Notice of Imposition of Civil Money Penalty for Program of All-inclusive Care for the Elderly (PACE) Alexian Brothers Community Services (H2609)

Dear Ms. White:

Pursuant to 42 C.F.R. §§ 460.40(a), 460.42(a) and 460.46(a)(4), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Alexian Brothers Community Services (Alexian), that CMS has made a determination to impose a civil money penalty (CMP) in the amount of \$25,000 for PACE contract number H2609.

CMS has determined that Alexian 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 and state regulators have been on site at Alexian three (3) times for monitoring visits/audits since May of 2012. These audits were conducted to determine if Alexian is in compliance with PACE regulations and guidelines.

CMS has determined that Alexian failed to monitor or assess the medical needs of Medicare and Medicaid enrollees, failed to develop and implement a patient care plan that met the needs of each participant's medical requirements and failed to maintain a single comprehensive medical record for each participant. Alexian's failures violate CMS requirements contained at §§ 1894 and 1934 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 and 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, 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 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 Alexian 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), and 460.106 (c) through (f). In numerous instances, auditors found that the care provided to Alexian enrollees was not compliant with national standards of care to measure and assess the progression of diseases as also required by the documented Alexian treatment protocol. Participant care was not appropriately monitored, managed or coordinated resulting in enrollees experiencing delays in or lack of medical testing required for the medical treatment for conditions such as diabetes, asthma and chronic obstructive pulmonary disease (COPD) and severe weight loss.

Noted deficiencies include, participants diagnosed with diabetes not receiving HgA1C blood sugar monitoring, or micro albumin urine testing, participants diagnosed with asthma or chronic obstructive pulmonary disease (COPD) not being provided lung function or blood oxygen saturation tests, and in one (1) instance a patient experienced significant weight loss (25 pounds) in three (3) weeks and was not assessed by the Primary Care Physician for proper treatment.

- Failure to develop and implement a patient care plan that met the needs of each participant's medical requirements in violation of 42 C.F.R. §§460.92, 460.98(a), 460.102(d), 460.104(b) through 460.104(e), and 460.106(a) through (f). Participants in the plan were not monitored or appropriately assessed and the care provided to the participants was not appropriately managed or coordinated. The lack of care coordination placed participants at risk of serious deterioration in their medical condition.
- 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. In numerous instances, enrollee medical records were found to be incomplete and housed in multiple locations, also lacking documentation of physician orders and laboratory test results. In addition, sections of the electronic record were disabled by a former employee.

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

Pursuant to 42 C.F.R. §§ 460.40(a) and 460.46(a)(4), CMS has determined that Alexian's violations of CMS PACE requirements are significant enough to warrant the imposition of a CMP. Alexian failed substantially to provide medically necessary items and services and that has adversely affected, or had the substantial likelihood of adversely affecting PACE participants.

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

Alexian may request a hearing to appeal CMS's determination in accordance with the procedures outlined in § 42 C.F.R. Part 422, Subpart T. Alexian 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 hearing must identify the specific issues and the findings of fact and conclusions of law with which Alexian disagrees. Alexian 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  
FAX: 410-786-6301

If Alexian 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. Alexian 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 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.

Ms. Beverly White

August 1, 2013

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If Alexian 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

cc: Judy Flynn, CMS/CMHPO/Region VII  
Delorse Mays, CMS/CMHPO/Region VII