**TO:** **All PACE Organizations**
**State Administering Agencies**
**RO/CO PACE team**

**DATE:** **December 10, 2004**

**RE:** **Sentinel Event Reporting Policy**

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## Purpose:

The purpose of the "Sentinel Event Reporting Policy" is to provide guidance to the PACE organizations regarding their responsibility should a sentinel event occur. This is one more tool to assist the PACE organization to find or prevent a gap in their systems and provide safe care to participants. CMS views these events as opportunities to conduct analyses of the underlying root causes, which will reduce the risk of recurrence of a similar event.

## Regulatory Section:

**Sec. 460.112(a)(1): Specific rights to which a participant is entitled.**
**(a) Respect and nondiscrimination.** Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

To receive comprehensive health care in a safe and clean environment and in an accessible manner.

**Sec. 460.136(a)(5): Internal quality assessment and performance improvement activities.**
**(a) Quality assessment and performance improvement activities.** A PACE organization must immediately correct any identified problem that directly or potentially threatens the health and safety of a PACE participant.

**Sec. 460.200(c): Maintenance of records and reporting of data.**
**(c) Reporting.** A PACE organization must submit to CMS and the State administering agency all reports that CMS and the State administering agency require to monitor the operation, cost, quality, and effectiveness of the program and establish payment rates.

## Definition:

A "**sentinel event**" is defined as an unexpected occurrence that caused a participant death or serious physical or psychological injury that included permanent loss of function. Included in this definition are any medical equipment failures that could have caused a death and all attempted suicides.

## Policy:

Should a sentinel event occur, the PACE organization shall inform CMS and the State administering agency within 24 hours of the occurrence or as soon as a determination is made that the occurrence may be a Sentinel Event. Should the event occur on a Friday, during the weekend or a holiday, notification shall be conveyed on the first workday after the event.

**Notification Procedure for PACE organization to CMS Central Office:**

- **Email CMS** at pace@cms.hhs.gov
- **Subject Line:** PACE Sentinel Event
- **Content of email: personal health information** should be limited to the following participant identifier: sex and age. Then describe very briefly what happened, when, and the disposition of the participant.
- **Give data** on how you can be reached

The PACE organization must initiate an investigation of the event and perform an intensive analysis. The following guidelines are provided to assist PACE organizations see beyond the immediate event to identify the systemic component that failed to prevent/avoid injury to a participant. CMS can provide technical assistance in the analysis process and in identifying the system component that failed.

PACE organization management shall probe the event details that may include, but are not limited to the following types of question guidelines:

- What was the nature of the event that occurred?
- To whom did it occur?
- What were the consequences of the event?
- What participant information is relevant to the event?
- Who were the parties involved, including persons witnessing the sentinel event?
- What was the location and circumstances of the event?
- Were there any mitigating circumstances?
- Was the event due to human error or mechanical defect?
- What other areas of service are/were impacted?
- Was the staff member appropriately trained and competent to perform or react to the situation leading to the sentinel event?
- Was all equipment inspected and maintained per manufacturer's instructions?
- Were there written policies and procedures in place? If such policies and procedures were in place, were they being followed at the time of the event?
- What factors internal to the PACE organization influenced the outcome of the event?
- What factors external to the PACE organization influenced the outcome of the event?
- What could have been done to prevent this event from occurring?
- What immediate action (if any) is necessary to stop any further negative outcomes?

After the PACE organization has collected all possible data regarding the event and determined the area of failure, they shall convene a meeting of the various disciplines, for the purpose of reviewing details of the sentinel event and exploring options to reduce or eliminate the risk of future occurrences. Finally,

policies and procedures shall be modified as appropriate, and used in the development of a corrective action plan.

The PACE organization is to notify CMS CO when it is ready to discuss its findings. The analysis will be discussed with CMS and the SAA via a conference call. At this time the PACE organization will have the opportunity to review the analysis that the team conducted and the improvements made.