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**DATE:** April 21, 2010

**TO:** PACE Organizations and PACE State Administering Agencies

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**SUBJECT:** PACE Level Two Reporting Guidance

The purpose of this memorandum is to issue updated guidance to PACE organizations and PACE State Administering Agencies (SAAs) on the reporting of serious events having adverse health outcomes for PACE participants. In this guidance, we have replaced the term “sentinel event” (used in the Sentinel Event Reporting Policy issued December 10, 2004), with the term “Level Two Reporting” which connotes a consequential effect on a PACE participant that requires timely reporting to CMS and the respective SAA.

Over the past several years, CMS analyzed and trended PACE sentinel events to identify common risks for frail elderly PACE participants and document the performance improvement activities undertaken by PACE organizations to reduce those risks by strengthening internal policies, processes, and operational systems. In conducting discussions with PACE organizations and analyzing national trends for serious reportable events, CMS recognized the need to clarify the events that meet the CMS threshold for serious consequences to a PACE participant that would trigger timely reporting to CMS and SAAs. The enclosed guidance reviews the regulatory requirements for external reporting of serious events and clarifies CMS’ expectations. The document also describes the investigative process for assisting PACE organizations in determining whether to report events in the aggregate as monitoring data (i.e., Level One Reporting via the Health Plan Management System) or as a single serious reportable event (i.e., Level Two Reporting). PACE organizations are expected to demonstrate, through examples of commonly occurring events, how to differentiate the two levels of external reporting.

This guidance is effective July 1, 2010. We will highlight the salient external reporting concepts contained in the guidance during the PACE User Group Call on April 22, 2010. We will also solicit comments from PACE organizations, PACE State Administering Agencies, the National PACE Association, and the public for a six-week comment period from April 22 – June 4, 2010 on the implementation of the Level Two Reporting guidance. We encourage all interested parties to send comments by June 4, 2010 to the dedicated PACE mailbox at [PACE\\_Level\\_Two\\_Comments@cms.hhs.gov](mailto:PACE_Level_Two_Comments@cms.hhs.gov).