



PACE Level Two External Reporting Guidance

October, 2010

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Preface

CMS acknowledges the significant input provided by staff from several PACE organizations and the National PACE Association in the development of this guidance.

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Introduction

This guidance provides PACE organizations with an overview of requirements to report both aggregate and individual level data to the Centers for Medicare and Medicaid Services (CMS) and State Administering Agencies (SAAs) for their use in monitoring PACE organizations' performance. ***This guidance effectively replaces the Sentinel Events Reporting Policy issued by CMS in 2004.*** In so doing, CMS is discontinuing use of the term "sentinel event" and adopting an external reporting paradigm that distinguishes between Level One and Level Two Reporting Requirements as described below.

Level One Reporting Requirements refer to those data elements for monitoring that are regularly reported by PACE organizations via the Health Plan Management System (HPMS) PACE monitoring module. These monitoring elements are detailed in the ***HPMS PACE User's Guide, Fall 2005*** and include: 1) routine immunizations; 2) grievances and appeals; 3) enrollments; 4) disenrollments; 5) prospective enrollees; 6) readmissions; 7) emergency (unscheduled) care; 8) unusual incidents; and 9) deaths. These data are often aggregated by reporting element to demonstrate program issues and trends. The HPMS database is regularly monitored by staff in the CMS Regional Office (RO) and State Administering Agency (SAA).

Data reported in response to the Level One Reporting Requirement are used by PACE organizations to identify opportunities for quality improvement. For example, based on their review of Level One data reported to HPMS, PACE organizations may:

- Conduct a Quality Assessment Performance Improvement (QAPI) activity using a standardized methodology (e.g., Plan, Do, Check, Act known as PDCA) if a policy or system problem is identified
- Institute QAPI-driven change in policies, procedures, systems, or training as appropriate
- Evaluate the effectiveness of the intervention
- Track and trend for sustainable improvement
- Reevaluate until improvement is sustained
- Document for review during CMS/SAA audit as evidence of a performance improvement activity
- Report findings at least annually to oversight committees including the PACE organization's governing board.

Level Two Reporting Requirements apply specifically to unusual incidents that result in serious adverse participant outcomes, or negative national or regional notoriety related to the PACE program. These incidents must be reported expeditiously on an individual basis via email to CMS to the dedicated PACE mailbox (pace@cms.hhs.gov) with copies to the RO and SAA. **Level Two incidents and the required reporting actions are detailed in this guidance. As explained above, this guidance replaces the Sentinel Events Reporting Policy issued by CMS in 2004 by: 1) specifying in greater detail the types of incidents that must be reported to CMS; and 2) identifying the circumstances in which reporting is required.**

CMS and SAAs partner with PACE organizations to enhance their internal quality assurance and risk management activities. Through the external reporting requirements, CMS and the SAA monitor the PACE organization's quality of care and risk reduction efforts. Refer to Appendix D for

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a brief overview of PACE organizations' internal quality assessment and performance improvement requirements and activities.

A key purpose in updating the Level II reporting requirements and processes is to support national consistency in PACE organization data collection and reporting, and in CMS responses and analyses of these data. CMS will periodically provide data reports and other feedback to the PACE Organizations based on these analyses.

Level Two Incidents and Reporting Thresholds

When unusual incidents meet specified reporting thresholds, PACE organizations are required to report them on a timely basis as Level Two Reporting Incidents to CMS Central (CO) and Regional (RO) Offices and the State Administering Agency (SAA). **Table 1** below, **Level Two Incidents and Reporting Thresholds**, identifies these incidents and related reporting thresholds. Level Two incidents require internal investigation and analysis of the occurrence by the organization with the goal of identifying systems failures and improvement opportunities. Most Level Two reports require the organization to conduct a root cause analysis. Information on conducting root cause analyses is detailed in this document.

Table 1: Level Two Incidents and Reporting Thresholds

Use this table with Glossary in Appendix A

Incident	Level Two Reporting Thresholds
Deaths	Unexpected outcome related to any unusual incident listed in this table Suicide (known or suspected) Homicide (known or suspected) Unexpected and with active coroner investigation
Falls: A sudden, often unexpected change in position, in which the person comes to rest unintentionally on the floor.	Resulted in death Resulted in injury requiring hospitalization of 5 days or more Resulted in injury for which the determination is made within 48 hours of the fall that permanent loss of function is expected
Infectious Disease Outbreak: An outbreak is 3 or more participant cases at a PACE Center, unless State law/regulation applies a more stringent standard.	All incidents of infectious disease outbreaks that meet the threshold of three or more cases (or the respective State standard if more stringent) linked to the same infectious agent within the same time frame (incubation, sub-acute, and acute manifestation) and are reportable to the respective State public health authority. Some situations may require additional reporting to the Centers for Disease Control and Prevention. Note: It is possible that a participant residing in a contracted facility could be affected by an outbreak there and may meet the Reporting Threshold for another Level Two reporting Incident, such as Unexpected Death.

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Table 1: Level Two Incidents and Reporting Thresholds

Use this table with Glossary in Appendix A

Incident	Level Two Reporting Thresholds
Pressure Ulcer: Acquired while enrolled in PACE	Unstageable Pressure ulcer Stage IV – Pressure ulcer with necrosis of soft tissue through to underlying muscle, tendon or bone Stage III – Pressure ulcer with full thickness skin loss involving damage or necrosis of subcutaneous tissue
Traumatic Injuries and/or other wounds that are not fall-related: (Excludes pressure ulcers)	Resulted in death Resulted in injury requiring hospitalization of 5 days or more Resulted in injury for which the determination is made within 48 hours of the injury that permanent loss of function is expected
Burns	Resulted in death Resulted in hospitalization (any length of inpatient stay) 3rd degree burn covering more than 10% of the body without hospitalization
Medication-related Occurrences: Mistakes that occur when prescribing, dispensing, or administering a medication	Resulted in death Resulted in hospitalization of 5 days or more Resulted in determination within 48 hours of the occurrence that permanent loss of function is expected Resulted in a near-death event, e.g., anaphylaxis, cardiac arrest
Adverse Drug Reactions: A serious adverse drug reaction is one that results in death, a life-threatening event, hospitalization, disability, or requires intervention to prevent permanent impairment or damage.	Any adverse drug reaction that meets the Food and Drug Administration (FDA) guideline for reporting under the FDA’s MedWatch program requires Level Two Reporting to CMS. More information regarding MedWatch reporting and the definition of a serious adverse drug reaction can be found on the FDA’s website at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
Adverse Outcomes: Serious, undesirable, and unexpected outcome of participant’s care or treatment that is not otherwise defined in this table.	Resulted in death Resulted in injury requiring hospitalization of 5 days or more Resulted in injury for which the determination is made within 48 hours of injury that permanent loss of function is expected
Restraint Use	Resulted in death Resulted in injury requiring hospitalization (any length of stay) Resulted in injury for which the determination is made within 48 hours of injury that permanent loss of function is expected
Elopement: Unexpected absence from a PACE-sponsored program setting. Applies to participants with documented cognitive deficit. See glossary.	All elopements in which a participant with a documented cognitive deficit is missing for 24 hours or more Resulted in death Resulted in any injury Resulted in injury for which the determination is made within 48 hours of occurrence that permanent loss of function is expected

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Table 1: Level Two Incidents and Reporting Thresholds

Use this table with Glossary in Appendix A

Incident	Level Two Reporting Thresholds
<p>Motor Vehicle Accidents: Applies to MVAs in which PACE participants were transported in a vehicle owned, contracted, or operated by PACE personnel.</p>	<p>Resulted in death Resulted in injury requiring hospitalization (any length of stay) Resulted in injury for which the determination is made within 48 hours of event that permanent loss of function is expected Resulted in injury requiring Emergency Department intervention without hospitalization, such as evaluation, suturing, splinting, or other treatment</p>
<p>Suicide Attempts</p>	<p>All suicide attempts</p>
<p>Food-borne infection outbreak: 3 or more cases of the same illness resulting from the intake of a similar food source.</p>	<p>All food-borne infection outbreaks that meet the threshold of 3 or more cases of the same illness resulting from intake of a similar food source and are reportable to the State public health authority</p>
<p>Fires/Other Disasters:</p> <p>An environmental event at a PACE-sponsored setting which requires evacuation or closure resulting in the inability to provide care, causes a significant disruption in care, or results in a loss of safe housing for a PACE participant.</p>	<p>Report burns or other injuries using the category guidelines in this table.</p>
<p>Equipment-Related Occurrences</p>	<p>Resulted in death Resulted in injury requiring hospitalization (any length of stay) Resulted in injury for which the determination is made within 48 hours of event that permanent loss of function is expected An equipment related occurrence that meets the FDA guideline for reporting under the FDA's MedWatch program requires Level Two Reporting to CMS. More information regarding MedWatch reporting can be found on the FDA's website: http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm</p>
<p>Media-related Event: The intention is to provide CMS with prompt notification, as CMS is frequently contacted for comments in these circumstances.</p>	<p>Any report of which the organization is aware through local, state, regional, or national media outlets (print, television or radio broadcast, web-based, radio, etc.) that presents a potential or actual harmful characterization of a PACE organization or the national PACE program (e.g., a local newspaper article on an investigation of reported elder abuse by a PACE staff).</p>

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Additional Reporting to Other Federal and State Health Authorities

In addition to required CMS and SAA reporting, PACE organizations also are required to report certain unusual incidents to other Federal and State agencies consistent with these agencies' requirements. For example:

- If a PACE organization *suspects* an incident of elder abuse, it must notify the appropriate State agency with oversight for elder affairs.
- Organizations experiencing an incident related to equipment failure or administration of medication to a participant that results in a serious adverse participant outcome are strongly encouraged to report the incident to the Federal Food and Drug Administration (through MedWatch on the FDA website).
- Organizations experiencing an infectious disease outbreak (three or more participants affected by the same agent in the same time period), caused by an agent such as Hepatitis A, must report the outbreak to the State public health agency with responsibility. In some situations, the State agency may instruct the organization to report concurrently to the Centers for Disease Control and Prevention.

The organization must make the notification(s) and take any prescribed actions within the prescribed timeframe to comply with applicable statutory or regulatory requirements. Specific requirements can be found on the respective Federal or State agencies' websites.

Process for Notification to CMS and SAA of Level Two Incidents

- 1) Within 48 hours of determining that the threshold for Level Two reporting has been met, notify CMS via e-mail at the dedicated PACE mailbox (pace@cms.hhs.gov) and copy the SAA and the RO.

All participant-specific events resulting in injury, requiring treatment or a change in the care plan must be documented in the medical record. The assessment determining likelihood of permanent loss of function should be completed within 48 hours and it must also be documented in the medical record by the Primary Care Physician or by the IDT within 48 hours. The assessment can take various forms consistent with accepted practice and PACE organization policies and procedures.

Examples:

- In the case of an incident resulting in a participant's death, the incident must be reported within 48 hours of the participant's death.
- In the case of an incident resulting in a hospitalization of five days or more, the incident must be reported within 48 hours of the 5th day of the hospital admission.
- In cases where a determination is made within 48 hours that permanent loss of function is expected, reporting must take place within 48 hours of such determination.

Content of E-mail notification:

- Subject Line: PACE Level Two Report.
- Provide the age and gender of participant involved.
- Identify the date and type of unusual incident, and the threshold for reporting, e.g., 87-year-old female participant experienced a fall on DATE which resulted in a hospitalization of five days or more.

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- Provide your contact information.

If the PACE organization is unsure of whether a threshold for Level Two reporting has been met, the organization will consult with its Account Manager **by telephone**. The organization's contact with the Account Manager must be made within 24 hours (or next business day) of determination that Level Two reporting may be required.

- 2) Undertake an internal investigation of the incident.** The investigation must be initiated within 24 hours of reporting the incident to CMS and the SAA, and must be concluded within 30 days of reporting the incident. If the internal investigation cannot be completed within 30 days, then prior to the 30-day deadline, the organizations must notify CMS by sending an email to pace@cms.hhs.gov with a copy to the SAA and the RO. The notification must describe the circumstances preventing completion of the investigation within the 30-day time period and provide information on when the investigation will be completed.

In general, it is expected that the organization's investigation will include a root cause analysis, as described below. There are instances, however, when the organization's staff may feel that a root cause analysis will not yield programmatic improvement information. If this is the case, the organization is to consult **promptly by telephone** with its Account Manager.

As discussed above, it is important to document all participant-specific events in the PACE medical record, particularly if they result in injury, require treatment or a change in the care plan. Documentation should include a statement of the event, an assessment, a diagnosis (if appropriate), any follow-up plans and participant progress. However, any specific details that relate to the investigation of the event (e.g., what were the contributing factors, was care inconsistent with policy, any concerns of quality, etc.) do not need to be included in the medical record. All such documentation should be kept separately in a Quality Assurance file.

- 3) Notify CMS via pace@cms.hhs.gov with a copy to the SAA and RO when the internal investigation is completed.** CMS will schedule a conference call within 30 days of this notification to discuss the organization's internal investigation, subject to the availability of key individuals from all entities. Any additional follow-up required subsequent to the call will be coordinated by the PACE organization, CMS RO and the SAA.

NOTE: If determination of likelihood of permanent loss of function is made more than 48 hours after the incident, (i.e. 72 hours, two weeks, etc.), the incident is NOT considered reportable as a Level II Reportable Event, but is considered a **“Loss of Functional Status Determined More Than 48 Hours After the Incident.”** It is important to capture such occurrences for trending and for CMS oversight purposes. All such determinations should be reported to the CMS Central Office PACE Nurse Consultant, via email to: (pacenurseconsultantco@cms.hhs.gov)

1. Subject Line: PACE Participant Fall **“Loss of Functional Status Determined More Than 48 Hours After Incident”**
2. Provide the age and gender of the participant involved
3. Identify date and type of unusual incident, and the threshold for reporting, e.g., 87- year-old female participant experienced an (*INSERT TYPE*) incident on DATE, (permanent loss of function determined > 48 hours after the incident)
4. Provide your contact information

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The CMS Central Office PACE Nurse Consultant will respond to the PACE organization within 7 business days to determine the next course of action, which is case-specific. PACE organizations are reminded that the intention is to collect accurate data for national program trending and care improvement, and that reporting these incidents is required. The SAA and Account Manager will be notified by the CO Nurse Consultant in these instances.

Format for Level Two PACE Organization Conference Call Case Presentation

When the PACE organization has completed its internal investigation of the incident meeting the threshold for Level Two Reporting, the organization must notify CMS via pace@cms.hhs.gov with a copy to the SAA and RO. The organization must prepare a case presentation for discussion on the call. When preparing the case presentation, the organization will include the following information in its discussion:

- Summary of the care history
- Age and gender of participant
- Date of enrollment into the program
- Significant diagnoses
- Participant's degree of involvement in PACE program
- IDT team's main concerns related to participant prior to event
- Summary of the event
- Precipitating/contributing factors
- Participant's involvement/actions surrounding the event
- Immediate actions taken
- Participant's status
- Working relationship with contracted facility, contracted services (if applicable)
- Compliance with organization's established policies and procedures
- Identification of risk points and their potential contribution to the event
- As appropriate, proposed improvements in policies, training, procedures, systems, processes, physical plant, staffing levels, etc. to reduce future risks

Process for Conducting Root Cause Analysis

A root cause analysis must be completed for events for which the PACE organization's staff, or staff in consultation with the CMS RO, determines the identified event is sufficiently serious that an in-depth understanding of how it could occur is essential, and/or multiple fail-safe measures are required as part of the organization's improvement plan. As described above, organizations are to consult with their Account Manager in cases where they believe a root cause analysis is not necessary.

1. There are many print and web-based resources to guide PACE staff in conducting a root cause analysis. Several essential elements are outlined below:

Describe the details of what happened. The description will help define the underlying problem.

- Who was involved?
- What were the circumstances of the event?
- When did it occur?
- Where did it happen?

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2. Identify the immediate factors that contributed to the event. This step enables the team to gather evidence. CMS recommends that the team asks why the event occurred and what relationships were associated with the defined problem. Specify factors that, if removed or changed, could prevent a recurrence.

- What were the human factors (staffing levels, knowledge, training, competency, fatigue, distractions, etc.)?
- Was the risk identified, adequately assessed, and a reduction strategy put in place prior to the incident (timely, comprehensive, documented, communicated to pertinent persons, etc.)?
- What were the equipment-related factors (maintenance, mechanical failure, age, operational history, etc.)?
- What were the environmental factors (lighting, noise, clutter, cleanliness, temperature, inspections, security, etc.)?
- What were the communication factors (adequate tools in place, in-service training, documented policies and procedures, reciprocal flow from/to management, information readily available, technical support, etc.)?

3. Develop a risk reduction strategy for each identified problem that differentiates effective solutions that meet team goals.

- Discuss the rationale if the team determines that no action should be taken.
- Develop and implement a corrective action if the team determines that a policy, procedure, system, training, or process should be improved.
- Design a performance measure to assess if the team's corrective action is effective and sustained over time.
- Define the period during which progress will be monitored for improvement.

4. Evaluate the effectiveness of corrective action

- Assess the improvement in performance.
- Revise the action plan accordingly.

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Appendix A: Glossary of Terms

The following terms are operational definitions used to assist PACE organizations in determining which unusual incidents should be reported as Level Two Reporting incidents.

Aggregate Data - Summary data obtained by totaling the single values from a collection of values meeting specific criteria. For example, the aggregate for deaths of participants in a quarter for a PACE organization would be the total number of participant deaths from all causes during the specified three month period.

Adverse Drug Reaction - A serious adverse drug reaction is one that results in death, a life-threatening event, hospitalization, disability, or requires intervention to prevent permanent impairment or damage. A serious adverse drug reaction will be reported as Level Two incident when the patient outcome meets the Food and Drug Administration (FDA) guideline for reporting a serious adverse event under the FDA's MedWatch program. More information regarding MedWatch reporting and the definition of a serious adverse drug reaction can be found on the FDA's website at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>.

Adverse Participant Outcome - A serious, undesirable, and unexpected outcome of participant's care or treatment.

Burn - An injury to tissue caused by heat, friction, electricity, radiation, or chemicals. Burns are characterized by degree, based on the severity of the tissue damage. A first-degree burn causes redness and swelling in the outermost layers of skin (epidermis). A second-degree burn involves redness, swelling and blistering, and the damage may extend beneath the epidermis to deeper layers of skin (dermis). A third-degree burn, also called a full-thickness burn, destroys the entire depth of skin, causing significant scarring. Damage also may extend to the underlying fat, muscle, or bone. The severity of the burn is also judged by the amount of body surface area (BSA) involved.

Death - Determination that a PACE participant has an irreversible cessation of circulatory and respiratory functions, or irreversible cessation of all functions of the entire brain, including the brain stem. This determination is made in accordance with State and Federal law.

Elopement – Elopement of a PACE participant occurs when a participant with cognitive deficits documented by the primary care physician and/or the IDT leaves PACE-sponsored setting without authorization and when this departure presents a threat to the safety of the participant or others. Application of the term elopement is limited to participants who have documented cognitive deficits, and to those who have been deemed incapable of making their own decisions about complying with documented treatment plans.

Equipment-related Occurrence - Equipment failure or malfunction is the failure of a medical equipment unit or device to meet its performance specifications or otherwise perform as the manufacturer intended. Common causes of medical equipment or device failure are lack of knowledge to operate it safely, instructions/labeling/packaging errors, defects, software problems, failure to work as intended, inappropriate interactions with other devices, or operator errors. PACE personnel must be alert to equipment failure that is likely to cause or contribute to a death or serious injury if it were to recur, and are strongly encouraged to voluntarily report such malfunction

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to the Food and Drug Administration at
<http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>.

Fall – A sudden, often unexpected change in position, in which the person comes to rest unintentionally on the floor

Fire/Other Disasters – An environmental event at a PACE-sponsored setting which requires evacuation or closure resulting in the inability to provide care, causes a significant disruption in care, or results in a loss of safe housing for a PACE participant

Hospitalization of 5 Days or More – A PACE participant requires an inpatient stay in an acute care medical or psychiatric facility for a minimum of 5 days or greater.

Improvement Activities - Activities undertaken by a PACE Organization in response to investigating unusual participant incidents or to correct program deficits. The organization follows its QAPI processes and its policies and procedures. The quality improvement focus can be at the organizational, provider team, or participant level. Examples include:

- Assessment of home delivery process for medication, with goals of increased safety and efficiency
- IDT develops a better falls risk assessment and prevention protocol
- Care plan modifications are made in response to a participant unusual event or near miss accident

Infectious Disease Outbreak - Three or more cases of the same illness resulting from the same source/ infectious agent. The focus of this element is participants at the PACE Center. It is possible that a participant residing in a contracted facility is affected by an outbreak there and may meet the Reporting Threshold for another Level Two reporting Incident such as Unexpected Death.

Level One Reporting - Level One Reporting is the set of required data elements reported to CMS and the State Administering Agency via entry into the Health Plan Management System (HPMS). These data elements are used to monitor PACE performance.

Level Two Reporting - Level Two Reporting is the discrete subset of unusual incidents identified in ***Table 1: Level Two Incidents and Reporting Thresholds*** in which the occurrence has a significant impact on the health and/or safety of a PACE participant, or the PACE program in the case of media-related events. These incidents are used to monitor the health and safety of the PACE participants and the effectiveness of the PACE organization's risk management and quality assurance programs.

Loss of Functional Status Determined More Than 48 Hours After Incident - If a determination of permanent loss of function is made more than 48 hours after an unusual incident (i.e. 72 hours, two weeks, etc.), the incident is **NOT** considered reportable as Level II but is considered a "Loss of Functional Status Determined More Than 48 Hours After Incident". Data definition of Level Two reporting requires use of this additional category. (See NOTE under "Process for Notification to CMS and SAA of Level Two Incidents" page 8)

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Media-related Incident - Any reporting through local, state, regional, or national media outlets (print, broadcast, web-based, radio, etc.) that presents a potential or actual harmful characterization of a PACE organization or program. The intention is to provide CMS with prompt notification, as CMS is frequently contacted for comments in these circumstances.

Medication-related Occurrences - Mistakes that occur when prescribing, dispensing, or administering a medication. Common causes of medication-related occurrences include confusion in the labeling of products, difficulty reading a prescriber's handwriting, misunderstanding a verbal medication order, patient misunderstanding, or ambiguities in product names or directions for use.

Participant - Individual enrolled in a PACE program.

Pressure Ulcer - Localized injury to skin and/or underlying tissue, usually over a bony prominence, as a result of pressure, or pressure in combination with shear force and/or friction (National Pressure Ulcer Advisory Panel).

Stage I	Persistent focal erythema without break in skin. NOTE: difficult to assess in darkly pigmented skin.
Stage II	Partial thickness of skin is lost and may appear as an abrasion, blister or shallow crater.
Stage III	Full thickness of skin is lost, exposing the subcutaneous tissue. It presents as a deep crater with or without undermining adjacent tissue.
Stage IV	Full thickness of skin and subcutaneous tissues are lost, exposing muscle, tendon or bone.
Unstageable	Ulcer bed contains too much necrotic tissue to visualize the true depth of the wound

Program-related Motor Vehicle Accident - Vehicle collision in which the vehicle is transporting PACE participants to or from a PACE program-related activity. Program-related activities include travel to and from the PACE Center, and community-based appointments/visits/excursions.

Restraint – Can be either physical or chemical.

- a. Physical restraint- A physical restraint is any manual method, mechanical device, or material attached or adjacent to the PACE participant's body that he/she cannot remove easily and which restricts freedom of movement or normal access to his/her body.
- b. A chemical restraint is a medication used to control behavior or to restrict the participant's freedom of movement and is not a standard treatment for the participant's medical or psychiatric condition.

Each PACE organization will develop a restraint policy and procedures, and train appropriate personnel to assess participants, apply restraints according to policy, and document all actions from assessment for restraint application to monitoring of the participant post-removal for the effectiveness of the intervention and the psychological and physical effects on the participant. CMS delineates several conditions that must be met

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when less restrictive methods fail and the IDT approves the use of restraints for the safety of the participant or others. These conditions include the following:

- (1) The restraint is applied for a defined, limited period of time, based upon the assessed needs of the participant.
- (2) Staff applying the restraint has been trained on the restraint policy and procedures, and uses safe and appropriate restraining techniques.
- (3) The restrained participant's condition must be continually assessed, monitored, and reevaluated.
- (4) The IDT removes the restraint at the earliest possible time.

Root Cause Analysis - A methodology that examines the causal factors pertinent to an incident involving a participant, and determines what internal improvements in systems and processes might be implemented to prevent a future occurrence.

Suicide Attempt - An act with a non-fatal outcome in which an individual deliberately initiates a behavior that, without intervention from others will cause self harm, or deliberately ingests a substance in excess of the prescribed or generally recognized therapeutic dosage that will cause self-harm.

Traumatic Injury - Physical damage to living tissue caused by the application of external force or violence (e.g., strike with an object, strike with a fist, etc.) that results in a bone fracture or soft tissue injury (bruise, strain, sprain, scrape, or cut in the skin).

Wound - A breach in the integrity of the external layer of skin resulting from a laceration, crushing trauma, abrasion, or puncture of the epidermis (external surface of the body).

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Appendix B: Examples of Level Two Reporting

The following examples are offered to assist PACE organization's in determining when incidents should be reported under Level One verses Level Two requirements. Incidents requiring Level Two Reporting are shaded.

Not all situations encountered by a PACE organization are expected to be covered by these examples. Organizations are expected to consult **by telephone** with their Account Manager for clarification as needed.

Participant Deaths

Note: For all participant deaths, PACE organizations must have an internal process for capturing data on each participant death, and reporting per HPMS guidelines.

Level Two Reporting refers to unexpected participant deaths having active coroner investigation, no clear explanation of cause, suicide, homicide, or an accidental death related to the other events identified in this guidance (falls, pressure ulcers, traumatic injuries, adverse drug reactions, medication occurrences, elopement, elder abuse, use of restraints, or other unexpected events). PACE organizations having difficulty determining whether a death requires Level Two Reporting should consult **by telephone** with their Account Manager.

<p>Incident:</p> <p>Expected deaths due to natural progression of disease or irreversibly compromised health status:</p> <ol style="list-style-type: none">1. 97-year-old participant receiving end-of-life care dies two months after being diagnosed with metastatic liver cancer.2. 87-year-old participant having congestive heart failure, diabetes, and end-stage renal disease dies after a progressive decline due to multi-system failure.	<p>Action: Level One Reporting</p> <p>The organization reviewed the cases internally and conducted any necessary improvement activities. The organization entered the incidents in the HPMS quarterly data report and utilized the data for QAPI activities as appropriate.</p>
<p>Incident:</p> <p>Unexpected deaths with active coroner involvement, no clear explanation for cause, or related to accidental event.</p> <ol style="list-style-type: none">1. 77-year-old participant was found dead in bed at his home. He had multiple diagnoses but no recent decline. Coroner was called, consulted with Medical Director, and after brief investigation concluded cause of death to be undetermined.2. 69-year-old participant was eating meat at an Assisted Living Facility and started to choke. <p>Abdominal thrusts were unsuccessfully applied. Participant was pronounced dead due to accidental asphyxiation.</p>	<p>Action: Level Two Reporting</p> <p>PACE organization notified CMS CO, RO, and SAA via e-mail within 48 hours of deaths per Level Two Reporting guidance (unexpected deaths). Organization investigated events and presented cases during conference call.</p>
<p>Occurrence with Additional Required Reporting:</p> <p>When death is unexpected due to accident, suicide, or homicide, follow State or County Coroner regulations.</p>	<p>Action:</p> <p>Follow State guidelines for reporting to State/County Coroner.</p>

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Falls

Falls present several unique challenges for reporting, such as confounding conditions or circumstances, the potential volume of reporting, difficulty assessing the circumstances of a fall not witnessed or occurring outside the PACE Center, and potential delay in identifying pathology causing or resulting from the fall. Several examples of falls have been developed to illustrate the level of required reporting. PACE organizations having difficulty determining whether a fall requires Level Two Reporting should consult **by telephone** with their CMS RO Account Manager.

<p>Incident:</p> <p>1. 72-year-old participant fell in PACE Center returning from the bathroom. She had no complaints of injury. A physical assessment revealed no soft tissue or bony structure injury, but the objective evaluation revealed a Urinary Tract Infection (UTI). Treatment with oral antibiotics was initiated that day and staff notified of potential fall risk.</p> <p>2. 68-year-old participant with multi-infarct dementia fell at the PACE Center. Post-fall examination revealed a recurrence of a previously resolved right hemi paresis. She had extensive soft tissue injury at the right hip, but no bony pathology. The initial prognosis was for full recovery, but participation with rehab was very limited due to cognitive impairment. She had not returned to baseline at 6 weeks.</p>	<p>Action: Level One Reporting</p> <p>The PACE organization reviewed the case internally and conducted any necessary improvement activities. The organization entered the incidents in the HPMS quarterly data report and utilized the data for QAPI activities as appropriate.</p>
<p>Incident:</p> <p>1. 75-year-old participant on Coumadin for a-fib fell getting out of bed at home. She had a bruise on her left forehead, and was more confused than baseline. She was referred to the ED for further evaluation, where INR found to be high and CT showed a left sided subdural hematoma. This was successfully evacuated; however, participant required acute hospital care for 8 days. A review of her PACE medical record indicated her last INR level was assessed six weeks ago. Although stabilized, she had not returned to baseline and was transferred to a SNF for skilled care.</p> <p>2. 80-year-old participant fell at home on Monday evening with subsequent inability to walk. She was found on the floor by the PACE home health aide who arrived on Wednesday morning to deliver personal care. She was transported by ambulance to the ED where x-rays revealed a right femoral neck fracture. She had no history of falls and no precipitating cause was identified. She underwent ORIF surgery the next morning, but developed post op complications. Eight days later, she was discharged to a contracted SNF for rehab. She was expected to return to her pre-fall baseline.</p>	<p>Action: Level Two Reporting</p> <p>Organization notified CMS CO, RO, and SAA via e-mail within 48 hours of reporting threshold (5th day of hospitalization in both cases.) Internal investigation was conducted and several care system improvements were presented on the conference call.</p>

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Pressure Ulcers

Pressure ulcers are defined as localized injury to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure, or pressure in combination with sheer force and/or friction (National Pressure Ulcer Advisory Panel). When determining the required level of reporting pressure ulcers, several points should be considered. States have well defined reporting criteria and processes, though not usually through the SAA. Staging and reporting requirements are based on incidence, not outcome or effect on the participant. Most pressure ulcers managed for nursing home residents heal within 60 days. Although not every pressure ulcer is preventable, the vast majority are. Provider assessment and documentation/reporting tools distinguish program-acquired from 'inherited' pressure ulcers. The National Pressure Ulcer Advisory Panel has developed staging that CMS has adopted to guide external reporting requirements for PACE organizations. PACE organizations having difficulty determining whether a pressure ulcer requires Level Two Reporting should consult **by telephone** with their CMS RO Account Manager.

<p>Incident: 82-year-old participant with functional decline was coming into the PACE Center less often. Home care staff reported that she required hands-on assistance to transfer and walk within her apartment. She lived alone. Assessment for pressure ulcers was positive for Stage I. IDT updated care plan and services, but 3 weeks later pressure ulcer on coccyx had progressed to Stage II. Interventions were intensified.</p>	<p>Action: Level One Reporting Organization reviewed the case internally and conducted any necessary improvement activities. Per current HPMS guidelines, the organization entered the incident in the HPMS quarterly data report (unusual incident) and utilized the data for QAPI activities as appropriate. While this case did not meet CMS pressure ulcer Level Two reporting threshold, it triggered a comprehensive assessment of current living situation, immediate interdisciplinary interventions, and increased oversight of contracted home care services. The organization followed State reporting guidelines.</p>
<p>Incident: A frail, terminally ill homecare participant became bed-bound. Indicators for multi-system failure and death within 2 to 4 months were present. Despite end-of-life services, and preventive measures the participant developed a stage III pressure ulcer which rapidly deteriorated. Aggressive wound care and pain control measures were established, but the wound worsened over a four week period. Debridement and increased wound care stabilized the pressure ulcer but it did not heal. Pain control was addressed. Participant died at home 3 months after becoming bed-bound, and 2 months after the pressure ulcer developed. The pressure ulcer was not considered a contributing factor to this expected death.</p>	<p>Action: Level Two Reporting Organization notified CMS CO, RO, and SAA via e-mail within 48 hours of reaching the reporting threshold (identification of Stage III pressure ulcer). QA department was notified. With rapid pressure ulcer progression, IDT conducted a root cause analysis in conjunction with the contracted VNA. The organization presented the case during a conference call with CMS/SAA when the investigation was completed. Organization must follow local pressure ulcer reporting guidelines. In some States, this incidence would be reported to the appropriate State agency at an earlier stage.</p>

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Traumatic Injuries

Reporting is based on an overall assessment of seriousness of the injury, incorporating the severity of the injury, its extent, and the type of interventions needed to treat the injury. See Glossary in Appendix A for definition. Outlined below are examples of reporting levels for traumatic injuries. PACE organizations having difficulty determining whether a traumatic injury requires Level Two Reporting should consult **by telephone** with their CMS RO Account Manager.

<p>Incident:</p> <p>1. In the PACE Center, a fight broke out between two participants over who gets to sit in the end seat at the table. The participants were separated by staff, but one had a 2 cm facial laceration from where her glasses were pushed into her face. The other was evaluated, but sustained no apparent injuries.</p> <p>2. During one evening, a participant was driving his personal occupancy vehicle which was struck from the side when another motorist ran a red light. There was a female passenger located in the vehicle that was also a PACE participant. Both participants were evaluated. The driver of the vehicle was upset, but denied injury. The PACE passenger was unable to move her arm due to shoulder pain. They were transported to the ED. #1 (driver) had no injury. #2 (passenger) had a dislocated shoulder which was reduced in the ED, and was then discharged home and scheduled for follow-up the next day in the PACE Center.</p>	<p>Action: Level One Reporting</p> <p>Organization reviewed the case internally and conducted any necessary improvement activities. The organization entered the incident in the HPMS quarterly data report and utilized the data for QAPI activities as appropriate.</p>
<p>Incident:</p> <p>A participant who lived alone was found by the van driver in the morning unconscious with evidence of being struck on the head, possibly during a home break-in. EMS transported participant to the hospital where a subdural hematoma was diagnosed and the participant was taken to surgery for evacuation. She was admitted to the intensive care unit and had fluctuating level of consciousness for 48 hrs post-op, but eventually stabilized. She was progressively moved to a floor bed, and then was discharged to rehab on hospital day 10. She recovered to her baseline by five months after the event.</p>	<p>Action: Level Two Reporting</p> <p>Organization notified CMS CO, RO, and SAA via e-mail within 48 hours of reaching the reporting threshold (fifth hospital day) per Level Two Reporting guidance. Organization investigated incident and presented case during conference call.</p>

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Medication-related Occurrences (other than Adverse Drug Reactions)

Medication-related occurrences are mistakes that occur when prescribing, dispensing, or administering a medication. PACE providers develop their pharmacy programs to prescribe, dispense, store, and administer the right medication to the right participant in the right dose, at the right time, and via the right route. Medication-related events that happen outside of the designed system are either categorized as a medication-related occurrence (if the medication is given) or a near-miss if the mistake is caught prior to administration. The identification of medication-related system failures is an essential PACE internal quality assurance responsibility.

<p>Incident: A participant had multiple diagnoses, including atrial fibrillation, for which she took Coumadin (Warfarin) 3 mg a day. She had also been increasingly tearful and withdrawn over the past several weeks and the social worker had discussed with her and the family the potential of depression. The team had even discussed it the same morning and the thought was to begin an antidepressant. Later that day the physician was busy in the clinic and the nurse approached him about the INR result of this participant (which was low) and also if he wanted to start the antidepressant. He responded “yes – let’s start with Celexa (thinking he would see the participant and would write an order then). The nurse (now thinking about the Coumadin) said “and what about the dose?” The physician gave a verbal order for 10 mg (thinking of Celexa – not Coumadin). The order was then written by the nurse for Coumadin 10 mg a day. Pharmacy did not question, but filled the order. Six days later the participant fell and developed a large hematoma on her thigh. Fortunately there was no head injury and no retroperitoneal bleed. She was admitted to the hospital, her coagulopathy was treated, she was transfused several units of blood and discharged home 2 days later. Her condition required intensive monitoring and care plan adjustments. She was expected to fully recover.</p>	<p>Action: Level One Reporting The organization reviewed the case internally and conducted any necessary improvement activities. The organization entered the incident in the HPMS quarterly data report and utilized the data for QAPI activities as appropriate.</p> <p>The QA department did a full investigation and developed a comprehensive corrective action plan which included a policy that in-person verbal orders must be verified by a signature (unless it is an emergency response) and that all phone verbal orders will be restated by the nurse taking the order and verified by the ordering physician or nurse practitioner.</p>
<p>Incident: A clinic nurse was administering medications in the PACE Center clinic. Several participants were sitting near the clinic to get their medications. One had an order for 40 units of NPH insulin. The nurse approached a participant she thought was the correct one and asked if she was “Mrs. Williams”. This individual nodded. The insulin was given and the participant returned to the Center. Because she had advanced dementia she did not object, or report the injection to anyone. Some 40 minutes later she became lethargic, then diaphoretic, and subsequently had a seizure. Staff called 911. She died en route to the hospital.</p>	<p>Action: Level Two Reporting Organization notified CMS CO, RO and SAA via e-mail within 48 hours of reaching the reporting threshold per Level Two Reporting guidance (medication related occurrence and unexpected participant death). Organization investigated the incident and presented the case during conference call. Root cause analysis identified several system improvements in medication safety policy and procedures, and staff competency assessment. The Organization presented the case and its actions in response to the incident during the conference call. The Organization cooperated fully with the coroner’s investigation.</p>

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Adverse Drug Reactions

An adverse drug reaction is a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function. The Food and Drug Administration maintains a drug safety database containing reports of serious adverse drug reactions entitled MedWatch. CMS advises PACE organizations to monitor this database because it provides important and timely medical product information to health care professionals, including information on prescription and over-the-counter drugs, biologics, medical devices, and special nutritional products.

<p>Incident: A 72-year-old female was started on Phenytoin (Dilantin) by a consultant neurologist for a tonic-clonic seizure that was felt to be related to a recent stroke. She was discharged from the hospital on Thursday with the new prescription for Phenytoin. Over the weekend she felt “flu-like” with sore throat, burning eyes and low grade fever. She was seen at the PACE clinic on Monday – noted to have a “hives-like rash”, with scattered blisters and multiple open lesions noted in her mouth. The diagnosis of Stevens-Johnson syndrome was made; the most likely cause was the newly started Phenytoin. She was admitted to the hospital and ultimately the intensive care unit for fluids, respiratory support, wound care and pain control. She was discharged to SNF 2 weeks later. Although her skin lesions resolved, she never regained the functional status she had prior to the event.</p>	<p>Action: Level Two Reporting Organization notified CMS CO, RO, and SAA via e-mail within 48 hours of reaching the reporting threshold per Level Two Reporting guidance (fifth hospital day). Organization investigated event and presented case during conference call.</p> <p>Additional External Reporting: Organization reported the occurrence through the MedWatch system.</p>
<p>Incident: A consultant cardiologist for the PACE program recently attended a conference on atrial fibrillation where a new medication, Rhythmex (facetious name) was announced. Over the course of the next 6 weeks, the consultant started four PACE participants on this drug. One participant died in his sleep approximately two weeks after beginning the medication, but it was thought to be a natural occurrence. However, when another participant had a sudden death event (also thought to be possibly expected) and a 3rd participant had a cardiac event in the Center that responded to CPR, it was felt that this could be a medication event. Rhythmex was stopped on all participants. The prescribing cardiologist was notified about these events.</p>	<p>Action: Level Two Reporting Organization notified CMS CO, RO and SAA via e-mail within 48 hours of reaching the reporting threshold (serious adverse drug reaction as defined by MedWatch reporting specifications) per Level Two Reporting guidance. The adverse reaction to medication was reported as an adverse drug reaction as soon as the pattern emerged. In consultation with the RO, reporting for the 3 involved participants was made separately. Organization investigated and presented the cases during the conference call.</p> <p>It was subsequently learned, through the MedWatch system, that Rhythmex did trigger potentially lethal arrhythmias; particularly in the frail elderly and that this was not identified in early safety testing.</p>

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Eloperments

Eloperment of a PACE participant is when a participant with documented cognitive deficits leaves a PACE-sponsored setting without supervision and when the departure presents a threat to the safety of the participant or others. CMS acknowledges the right of a PACE participant to leave the PACE center at will when mentally capable to do so. Therefore, the application of the term elopement for the purposes of Level Two Reporting is limited to participants whose medical conditions result in cognitive deficits, or, to those who have been deemed legally incapable of making their own decisions about complying with documented treatment plans.

<p>Incident: A participant having a history of traumatic brain injury related to a motor vehicle accident experiences frequent episodes of residual memory and visual-spatial ability deficits, and disorientation. She left the PACE Center unnoticed by any staff. When the staff realized the participant was no longer in the Center, they implemented appropriate policies and procedures to locate the participant. She was found a few hours later in a confused state, but had no injuries.</p>	<p>Action: Level One Reporting The organization reviewed the case internally and conducted any necessary improvement activities. Organization entered the incident in the HPMS quarterly data report and utilized the data for QAPI activities as appropriate. A review of the participant's care plan indicated she required frequent monitoring. The participant's care was subsequently revised to include the issuance of a wandering guard device.</p>
<p>Incident: A PACE participant who had been identified as at risk for wandering left the PACE Center without the knowledge of PACE Center staff. He was located by PACE staff several hours later. Due to inclement weather, when he was found his clothes were wet and he had signs and symptoms of hypothermia. He was brought back to the PACE Center where his condition was immediately assessed by the physician who determined the participant required hospital admission. The participant was discharged after a six-day hospital stay for treatment of a lower respiratory infection. He fully recovered within two weeks.</p>	<p>Action: Level Two Reporting The CO, RO, and SAA were notified via e-mail within 48 hours of reaching the reporting threshold (fifth hospital day) per Level Two Reporting guidance. The organization presented the case during the conference call. Staff undertook a thorough internal investigation of the incident including a root cause analysis. The analysis revealed that a monitoring device was not provided to the participant as required by his plan of care. The policy was revised to incorporate a process to assure that monitoring devices are appropriately applied on a daily basis and staff is trained accordingly. A process for random, ongoing assurance of compliance was implemented.</p>

Restraints

PACE regulation §460.114 stipulates that, if the interdisciplinary team (IDT) determines that a restraint is needed to ensure the participant's physical safety or the safety of others, the organization must limit the use of restraints to the least restrictive and most effective method available. Although CMS expects organizations to try alternative methods of achieving a safe environment or safe participant behavior, PACE regulations do permit the limited use of either a physical or chemical restraint. Examples of unusual incidents involving the use of restraints are illustrated below. PACE organizations having difficulty determining whether an incident related to restraint use requires Level Two Reporting should consult **by telephone** with their CMS RO Account Manager.

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<p>Incident: A 72-year-old female participant residing in a skilled nursing facility (SNF) had a history of diabetes, hypertension, multiple sclerosis, and a cerebrovascular accident with right-sided hemiparesis and aphasia. Her husband visited the facility daily and assisted staff with transferring her to a geri-chair and feeding her. His most recent visit was delayed because he had an appointment prior to going to the SNF. When he arrived at the facility and entered her room, he saw her suspended from a lap belt in her chair with her arms outstretched above the belt and her lower body slumped on the floor. After extensive evaluation over the next few days, her provider determined she had brachial plexus neuropathy in her left arm; a permanent loss of function was not expected.</p>	<p>Action: Level One Reporting The PACE organization reviewed the case internally and conducted any necessary improvement activities. The organization entered the incident in the HPMS quarterly data report and utilized the data for QAPI activities as appropriate. The PACE organization consulted with the SNF as the facility conducted its quality assurance investigation. The PACE organization received a report on the investigation findings. The organization sent nursing staff and the QAPI coordinator to review the care of all other participants residing in the SNF. The QAPI coordinator also conducted refresher training for personnel with contractor oversight responsibilities on the policies, procedures, safe use of restraints and monitoring in contracted facilities.</p>
<p>Incident: An 83-year-old male participant having a history of coronary artery disease with a bypass graft, chronic anemia, osteoarthritis, and chronic prostatitis fell as he descended his basement stairs, and was unable to walk. His wife called emergency services and he was transported to the hospital. The participant was admitted for treatment of a hip fracture, underwent a hip replacement and was transferred to a SNF on hospital day 4. On his first day at the SNF, he became confused and agitated. He tried to get out bed to use the bedside commode despite having been told repeatedly to ask for help. He was highly distractible and disoriented. The staff physician initiated a low dose course of haloperidol to treat his delirium. His bedrails were raised to prevent him from falling out of bed. During rounds that night, the nurse found him face-down between the bedrail and mattress. She assessed him to be unresponsive and signaled for a code team since his status was full code. Resuscitation efforts were unsuccessful, and the PACE physician was notified of his death.</p>	<p>Action: Level Two Reporting Organization notified CMS CO, RO and SAA via e-mail within 48 hours of reaching the reporting threshold per Level Two Reporting guidance. (In this case, the death was unexpected, and felt primarily related to the bedrail restraint. The haloperidol dose was low, and not considered a contributing factor in the death.) The organization consulted with the SNF as it conducted a root cause analysis. Since the organization had maintained a collegial working relationship with the SNF, the PACE clinical leaders were able to share research showing that the use of bedrails did not prevent falls and resulted in an increase of injuries among elderly patients. The organization requested that the SNF consider the FDA recommendations to reduce the risk for bedrail entrapment. The QAPI coordinator conducted refresher training for PACE personnel on preventing bedrail entrapment. Additional oversight in this SNF was instituted. When the investigation was concluded, the organization presented case during conference call.</p>

Media-related Incidents

A media-related incident is any reporting through local, state, regional, or national media outlets (print, broadcast, web-based, radio, etc.) that presents a potential or actual harmful characterization of a PACE organization or the PACE program. The PACE organization must notify its contractual partners and sponsors, CMS and SAA, when adverse publicity that it is aware of could reflect poorly on either the local and/or national program. CMS and the respective SAA have the obligation to maintain public trust and accountability to funding authorities. Timely notification by the PACE organization enables CMS and SAA to collaborate in transmitting an accurate and dispassionate perspective of the PACE program.

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Incident:

The PACE director received a call from a reporter; he had some questions about the corrective action plan that CMS posted to its web site. The plan called for corrective actions regarding day center attendance, supervision of home care staff, and proper handling of controlled substance prescriptions. The reporter had done past stories on poor quality care in community nursing homes and assisted living facilities. The tone of the questions indicated that he was planning to write a story critical of the PACE program. The PACE CEO invited him to visit the PACE Center and talk with participants, staff, or caregivers willing to be interviewed. The reporter subsequently published a feature article in the local newspaper that was disparaging and focused only on perceived problems.

Action: Level Two Reporting

Because of the timeline, the PACE director decided to alert her CMS RO and SAA contact that a reporter was writing a story that would *likely* have a negative tone. At the same time, the organization notified CMS CO, RO and SAA via e-mail within 48 hours of becoming aware of potentially negative publicity per Level Two Reporting guidance.

The Account Manager agreed with the organization that a root cause analysis would not be useful and together they agreed on a joint action plan for the PACE organization and community supporters to counteract the biased presentation in the article. CMS RO leadership was alerted. RO management discussed with SAA management. The PACE organization presented the case on subsequent teleconference with CMS and SAA. Actions taken and known outcomes were discussed on the call.

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Appendix C: Quality Assessment and Performance Improvement (QAPI) Information

PACE Quality of Care and Safety

At the PACE organization level, quality assessment and performance improvement begins with the development of the QAPI plan and its related policies and procedures that assure quality of care, a safe environment, competent personnel, and the delivery of appropriate and timely services using recognized standards of professional practice. PACE organization leaders oversee implementation of the established QAPI policies and protocols, and develop the specific health outcome measures that inform them whether their policies and operational systems effectively result in safe and high quality care.

By virtue of being a full-service program targeting the vulnerable frail elderly, PACE leaders face unique challenges. An effective QAPI program requires continuous surveillance by all stakeholders (employed and contracted staff, caregivers, and participants) of the range of PACE services. CMS believes the designation of a dedicated QAPI coordinator is imperative to conduct continuous performance improvement activities that inform the organization leadership ultimately responsible for care delivery including, but not limited to, ambulatory, home health, adult daycare, long-term, acute, emergency, and restorative services. Within these domains of care, leaders oversee multiple disciplines internally – medical, nursing, social, mental health, recreation therapy, dietary, restorative therapies, transportation – as well as specialized services in the community.

An essential component of an effective quality improvement program is risk assessment and management. Risk management entails identifying and systematically reducing potential risks to the safety of PACE participants and the healthcare environment. Risk assessment ideally is conducted prospectively to prevent occurrences that result in adverse health outcomes to participants or staff, or harm to the organization's physical plant/equipment or fiscal status. In reality, risk assessment is most often conducted in response to an event that results in medical, psychosocial, cognitive, or functional harm to a participant or staff. Every person employed or contracted by the organization has responsibility for risk assessment and management.

CMS and SAAs partner with PACE organizations to enhance internal quality assurance and risk management activities. Through the external reporting requirements, CMS and the SAA monitor the organization's quality of care and risk reduction efforts. External monitoring activities refer to both the submission of the monitoring data elements via the PACE monitoring module of the HPMS (Level One Reporting), and the reporting of events resulting in significant harm to participants, or negative national or regional notoriety related to the PACE program (Level Two Reporting).

Internal Quality Assessment and Performance Improvement (QAPI) Requirements

In the Program of All-inclusive Care for the Elderly (PACE) Final Rule (42 CFR 460) published December 8, 2006, the Centers for Medicare & Medicaid Services (CMS) authorized the PACE organization, the State Administering Agency (SAA), and CMS to cooperatively develop and implement health status and quality of life outcome measures pertinent to PACE participants. It mandated that PACE organizations develop and implement a data-driven quality assessment and performance improvement program (QAPI). Through the QAPI program, organizations must evaluate the effectiveness of the wide range of services furnished by PACE organizations, and use

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data to identify and improve areas of poor performance (§460.130). CMS believed that each organization should have the flexibility to design an *internal* QAPI program that would best meet the needs of its enrolled participants and their caregivers; therefore, CMS neither specified a standardized quality assessment tool nor dictated the data-driven outcome measures that organizations should internally collect, analyze, and act on to improve performance. However, CMS did provide in §460.132 the minimum requirements that must be addressed in the organization's written plan for the internal QAPI program including the requirement that the plan be annually reviewed and revised by the respective PACE governing body to assure organizational oversight and commitment.

CMS also devised minimum QAPI program requirements (§460.134) to develop outcome measures related to five areas: 1) utilization of services, 2) participant and caregiver satisfaction, 3) data collected during participant assessments, 4) effectiveness and safety of direct and contracted services delivered to participants, and 5) non-clinical areas including grievances and appeals. It gave further guidance in §460.136 to set QAPI priorities (i.e., the QAPI program must measure clinical outcomes), assign a QAPI coordinator, and involve all stakeholders in the QAPI program.

Overview of External Reporting Requirements

In its Final Rule, CMS acknowledged its duty to hold each PACE organization accountable for its QAPI activities. As PACE organizations began to transition from original demonstration projects to permanent PACE providers in 2001, CMS structured a performance monitoring mechanism in accordance with §460.140 (additional quality assessment activities) by establishing nine monitoring data elements that PACE organizations were required to regularly report via entry in the Health Plan Management System (HPMS). CMS further expanded its monitoring capacity under this regulation when it published an *external* sentinel event reporting policy on December 10, 2004.

CMS is herein clarifying the external reporting requirements described in the 2004 publication *Sentinel Events Reporting Policy*. CMS has discontinued the use of the term "sentinel event" and adopted an external reporting paradigm that consists of two reporting levels.

Level One reporting encompasses the nine monitoring elements that are regularly reported in the HPMS PACE monitoring module. These monitoring elements are detailed in the *HPMS PACE User's Guide, Fall 2005*, and are outlined below.

Level Two reporting identifies significant events having adverse participant outcomes that must be electronically reported to CMS via the dedicated PACE mailbox (pace@cms.hhs.gov) and copied to the SAA. These significant events and the required reporting actions are detailed in this guidance document.

Level One Reporting, CMS Regional Office (RO) & State Administering Agency (SAA)
PACE organizations conduct Level One Reporting via the entry of the required data elements into the PACE monitoring module of the Health Plan Management System (HPMS) on a quarterly basis. In the preamble of the PACE Final Rule (42 CFR 460, December 8, 2006), CMS identified these nine monitoring data elements as:

- routine immunizations
- grievances and appeals
- enrollments

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- dis-enrollments
- prospective enrollees
- readmissions
- emergency (unscheduled) care
- unusual incidents for participants and the PACE site (to include staff if a participant was involved)
- deaths

Unusual incidents that result in no harm or a relatively low acuity of injury are appropriate for Level One Reporting. These incidents are reviewed locally to determine whether a QAPI activity is warranted, and may result in the organization taking one or more of the following actions:

- Conduct a QAPI activity using a standardized methodology (e.g., Plan, Do, Check, Act known as PDCA) if a policy or system problem is identified
- Institute QAPI-driven change in policy, procedures, systems, or training as appropriate
- Evaluate the effectiveness of the intervention
- Track and trend for sustainable improvement
- Reevaluate until improvement is sustained
- Document for review during CMS/SAA audit as evidence of a performance improvement activity
- Report findings at least annually to oversight committees including the governing board.

Level One data elements are entered in HPMS per instructions found in the HPMS User's Guide (Fall 2005). The HPMS database is regularly monitored by the respective CMS Regional Office (RO) and State Administering Agency (SAA).

Level Two Reporting Central / Regional Offices & State Administering Agency

When unusual incidents result in adverse participant outcomes, and meet reporting thresholds, they are classified as Level Two Reporting incidents. These events occur at the individual level and require timely reporting to CMS Central (CO) and Regional (RO) Offices and the State Administering Agency (SAA) when the event is determined to meet the threshold of Level Two Reporting outlined in **Table 1: Incidents and Thresholds for Level Two Reporting** in this document. Level Two incidents usually **require** internal investigation and analysis of the occurrence by the organization with the goal of identifying system failures and improvement opportunities. Most Level Two reports require the organization to conduct a root cause analysis. The PACE Organization presents the case on a teleconference with CMS and the SAA at the conclusion of their investigation.

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Appendix D: References

Agency for Healthcare Research and Quality

- Clinical practice guidelines
- Preventing medical errors
- Quality care
- Safe care

<http://www.ahrq.gov>

Centers for Disease Control and Prevention

- Injury, violence and safety
- Older adults and seniors health issues
- Research publications

<http://www.cdc.gov>

Centers for Medicare & Medicaid Services

- Quality initiatives and research

<http://www.cms.gov>

PACE regulations (42 CFR 460)

<http://www.gpoaccess.gov/CFR/>

Food and Drug Administration

- Drug safety
- Medical device and equipment safety
- MedWatch reporting

<http://www.fda.gov>

Institute of Medicine

- Aging issues
- Healthcare and quality issues
- Research publications

<http://www.iom.edu>

The Joint Commission

- Participant safety
- Root cause analysis process
- Sentinel event alert reports

www.jointcommission.org

National Pressure Ulcer Advisory Panel

- Research and guidelines on pressure ulcer management

<http://www.npuap.org>

National Institute of Aging

- Research publications
- Safety issues

<http://www.nia.nih.gov>

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Pharmacy Related Resources:

- **Institute for Safe Medication Practices** <http://www.ismp.org/>
- **National Association of Boards of Pharmacy
Links to State Boards** <http://www.nabp.net/>
- **American Society of Consultant Pharmacists
(LTC Pharmacists)** <http://www.ascp.com/>