PACE Level II Reporting Guidance

September 2013

Table of Contents

Introduction

This guidance provides PACE organizations (POs) 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 POs' performance.
We have revised several definitions and added new definitions for reportable Level II incidents. We also have modified the threshold for reporting certain occurrences. Please see Appendix A, Definitions of Terms for Level II Reporting.

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

Level I Reporting Requirements refers to those data elements for monitoring that are regularly reported by POs via the Health Plan Management System (HPMS) PACE monitoring module. These monitoring elements are detailed in the ***HPMS PACE User's Guide, Fall 2008*** 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.

CMS expects POs to use the data reported in response to the Level I Reporting Requirement to identify opportunities for quality improvement. For example, based on their review of Level I data reported to HPMS, POs may:

- Conduct a Quality Improvement (QI) activity using a standardized methodology (e.g., Plan, Do, Check, Act known as "PDCA")
- Institute QI-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 PO's governing board.

Level II 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. POs are required to report incidents within 2 working days to CMS Central (CO) and (RO) Offices and the SAA via the dedicated PACE mailbox **(pace@cms.hhs.gov)**. **This guidance details Level II incidents and the required reporting actions.** CMS and SAAs partner with POs to enhance their internal quality assurance and risk management activities. Through the reporting requirements, CMS and the SAA monitor the PO's quality of care and risk reduction efforts. Refer to Appendix B for a brief overview of PO's internal quality improvement requirements and activities.

Level II Incidents and Reporting Thresholds

Table 1 below, **Level II Incidents and Reporting Thresholds**, identifies these incidents and related reporting thresholds. Level II incidents require internal investigation and analysis of the occurrence by the PO with the goal of identifying systems failures and improvement opportunities. Most Level II reports require the PO to conduct a Root Cause Analysis. Please see page 9 for information on conducting Root Cause Analysis.

Table 1: Level II Incidents and Reporting Thresholds

Use this table with Definition of Terms for Level II Reporting in Appendix A	
Incident	**Level II Reporting Thresholds**
Deaths	Death related to the following: • Homicide (known or suspected) • Clinical Manifestations (terminal illness, natural causes, organ failure [ex. brain, liver, kidney, lung]) • Sepsis
Falls	Resulted in death Resulted in a fracture Resulted in injury requiring hospitalization related directly to the fall Resulted in injury for which permanent loss of function is expected
Infectious Disease Outbreak	Resulted in death 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 (CDC). 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 II reporting incident, such as unexpected death.
Pressure Ulcer acquired while enrolled in PACE	Unstageable Deep Tissue Injury Stage IV Stage III
Abuse including self-inflicted and physical, financial, verbal, emotional, or sexual	Resulted in death Resulted in injury requiring hospitalization related directly to the abuse or assault Resulted in a fracture Resulted in completing mandated report per state requirement, including suspicion of abuse/assault Resulted in injury for which the determination is made that permanent loss of function is expected
Burns	Resulted in death Resulted in hospitalization

Use this table with Definition of Terms for Level II Reporting in Appendix A	
Incident	**Level II Reporting Thresholds**
Medication-related Occurrences	Resulted in death Resulted in injury requiring hospitalization related directly to the medication-related occurrence Resulted in a near-death event, e.g., anaphylaxis, cardiac arrest Resulted in injury for which the determination is made that permanent loss of function is expected
Adverse Drug Reactions	Any adverse drug reaction that meets the Food and Drug Administration (FDA) guideline for reporting 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 Outcomes	Resulted in death Resulted in injury requiring hospitalization related directly to the adverse outcome. Resulted in a fracture Resulted in a participant's Advance Directive not being followed (e.g. Participant Advance Directive stated 'perform CPR' and CPR was not performed or Advance Directive stated 'DNR' and participant was resuscitated) Resulted in injury for which the determination is made that permanent loss of function is expected
Restraint Use	Resulted in death Resulted in injury requiring hospitalization related directly to restraint use Resulted in injury for which the determination is made that permanent loss of function is expected
Elopement	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
Motor Vehicle Accidents	Resulted in death Resulted in injury requiring hospitalization related directly to motor vehicle accident Resulted in injury requiring Emergency Department intervention without hospitalization, such as evaluation, suturing, splinting, or other treatment. Resulted in injury for which the determination is made that permanent loss of function is expected
Suicide Attempts	All suicide attempts Resulted in death
Food-borne infection outbreak	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

Use this table with Definition of Terms for Level II Reporting in Appendix A	
Incident	**Level II Reporting Thresholds**
Fires/Other Disasters	Report burns or other injuries using the category guidelines in this table
Equipment-Related Occurrences	Resulted in death Resulted in injury requiring hospitalization related directly to equipment-related occurrence Resulted in injury for which the determination is made that permanent loss of function is expected An equipment related occurrence that meets the FDA guideline for reporting under the FDA's MedWatch program. More information regarding MedWatch reporting can be found on the FDA's website: **http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm**
Media-related Event	Any report of which the PO 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 PO or the national PACE program (e.g., a local newspaper article on an investigation of reported elder abuse by a PACE staff).

Additional Reporting to Other Federal and State Health Authorities

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

- If a PO *suspects* an incident of elder abuse, it must notify the appropriate State agency with oversight for elder affairs.
- POs 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 FDA (through MedWatch on the FDA website).
- POs experiencing an infectious disease outbreak (three or more participants affected by the same agent in the same time period), must report the outbreak to the State public health agency with responsibility. In some situations, the State agency may instruct the PO to report concurrently to the CDC.

The PO 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 Level II Notification to CMS and SAA and Completion of Internal Investigation

1) **Notify CMS and the SAA.** Within 2 working days of determining that the threshold for Level II reporting has been met, notify CMS via e-mail at the dedicated PACE mailbox (pace@cms.hhs.gov) and copy the SAA.

   All participant-specific events resulting in injury, requiring treatment or a change in the plan of care must be documented in the medical record. The assessment determining likelihood of permanent loss of function must be completed within 2 working days and must also be documented in the medical record within 2 working days. The assessment can take various forms consistent with accepted practice and PO policies and procedures.

   Content of initial E-mail notification:

a) Subject Line: PACE Level II Report
b) Type of incident
c) Location of incident
d) Participant's current status
e) Significant diagnoses
f) Summary of the care history
g) Summary of the event
h) Reported to other Federal or State health authorities
i) Provide complete contact information (e.g., name, PO, phone number, and email)

Example:

a) Subject Line: PACE Level II Report
b) Fall
c) Home
d) Critical
e) HTN, DM, Osteoporosis, ESRD, syncope
f) Participant has had 6 falls in the past 12 months
g) Participant was walking from bathroom to the bedroom without walker and fell in hallway. Participant hit their head on the wall. Participant was unable to get up and pushed emergency alert button for assistance. EMS arrived and transported participant to emergency department. Participant is currently in the ICU with hip, rib, and ankle fractures and a subdural hematoma.
h) Department of Health and Mental Hygiene notified on May 6, 2014
i) James Jones
Quality Improvement Coordinator
PACE Orlando Florida
407-555-1234
James.jones@paceorlando.org

CMS may request that the PO conduct a full Root Cause Analysis. If CMS determines that a Root Cause Analysis is needed, CMS will send an email to the PO to initiate an internal investigation. The email will include a CMS-assigned case number which must be included in all correspondence regarding the incident.

If the PO is unsure of whether a threshold for Level II reporting has been met, it may consult with CMS by sending an email to **pace@cms.hhs.gov**. The PO's contact with CMS must be made by the next business day of determination that Level II reporting may be required.

2) **Conduct Root Cause Analysis**. When CMS asks the PO to conduct a Root Cause Analysis, the PO must initiate an investigation within 24 hours of reporting the incident to CMS and the SAA. The analysis must be concluded within 30 working days of reporting the incident. If the analysis cannot be completed within 30 working days, the PO must notify CMS by sending an email to **pace@cms.hhs.gov** with a copy to the RO AM and the SAA. The notification must describe the circumstances that prevented completion of the investigation within the 30 working day time period and provide information on when the analysis will be completed. CMS will then provide the PO with an extended timeframe to complete their Root Cause Analysis.

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 RO AM and the SAA of the completed analysis.** The RO AM will schedule a conference call within 30 working days to discuss the PO's internal investigation, subject to the availability of key individuals from all entities.

Format for Level II PACE Organization (PO) Conference Call Case Presentation

When the PO has completed its Root Cause Analysis, the PO must notify CMS via **pace@cms.hhs.gov**with a copy to the RO AM and the SAA. The PO must prepare a case presentation for discussion on the call. When preparing the case presentation, the PO will include the following information in its discussion:

1. Case number
2. Age and gender--**optional**
3. Enrollment date--**optional**
4. Participant's current status
5. Significant diagnoses
6. Summary of the care history
7. Summary of the event
8. Immediate actions taken
9. IDT team's main concerns related to participant prior to event
10. Precipitating/contributing factors
11. Participant's involvement/actions surrounding the event
12. Participant's degree of involvement in PACE program
13. Working relationship with contracted facility, contracted services (if applicable)
14. Compliance with PO's established policies and procedures
15. Identification of risk points and their potential contribution to the event
16. As appropriate, quality improvement projects, proposed improvements in policies, training, procedures, systems, processes, physical plant, staffing levels, etc. to reduce future risks

This non-identified information must be included in an unencrypted email notification to the SAA and CMS prior to the call.

Process for Conducting Root Cause Analysis

The PO must conduct a Root Cause Analysis for events for which the PO's staff, or staff in consultation with CMS, determines the identified event is sufficiently serious that an in-depth understanding of how it occurred is essential, and/or multiple fail-safe measures are required as part of the PO's quality improvement plan.

Rescinding a Level II Incident

If at any time during the investigation, a Level II does not meet the Level II Reporting Thresholds as listed in **Table 1 Level II Incidents and Reporting Thresholds**, the PO should notify CMS via pace@cms.hhs.gov. The email should include the case number and reason for rescinding the Level II incident.

Appendix A: Definition of Terms for Level II Reporting

The following terms are operational definitions used to assist PACE organizations (POs) in determining which unusual incidents should be reported as Level II incidents.

Abuse: The willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain, mental anguish, or death. This also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being.

The National Center of Elder Abuse[1] defines 3 categories of elder abuse:

- *Domestic Elder Abuse*: Domestic elder abuse generally refers to any of several forms of maltreatment of an older person by someone who has a special relationship with the elder (a spouse, a sibling, a child, a friend, or a caregiver), that occur in the elder's home, or in the home of a caregiver.
- *Institutional abuse*, on the other hand, generally refers to any of the above-mentioned forms of abuse that occur in residential facilities for older persons (e.g., nursing homes, foster homes, group homes, board and care facilities). Perpetrators of institutional abuse usually are persons who have a legal or contractual obligation to provide elder victims with care and protection (e.g., paid caregivers, staff, and professionals).
- *Self-Neglect or Self Abuse:* is characterized as the behavior of an elderly person that threatens his/her own health or safety. Self-neglect generally manifests itself in an older person as a refusal or failure to provide himself/herself with adequate food, water, clothing, shelter, personal hygiene, medication (when indicated), and safety precautions.

Abuse may include the following:

***Verbal Abuse**:* the use of oral, written, or gestured language that willfully includes disparaging and derogatory terms to patients or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. *Examples of Verbal Abuse:* Threats of harm, saying things to frighten a patient, (e.g. such as telling a patient he will never see his family again)

***Emotional or Psychological Abuse**:* the infliction of anguish, pain, or distress through verbal or nonverbal acts. Emotional/psychological abuse includes but is not limited to verbal assaults, insults, threats, intimidation, humiliation, and harassment. In addition, treating an older person like an infant; isolating an elderly person from his/her family, friends, or regular activities; giving an older person the "silent treatment;" and enforced social isolation are examples of emotional/psychological abuse.

***Sexual Abuse**:* non-consensual sexual contact of any kind with an elderly person. Sexual contact with any person incapable of giving consent is also considered sexual abuse. It includes, but is not limited to, unwanted touching, all types of sexual assault or battery, such as rape, sodomy, coerced nudity, and sexually explicit photographing.

[1] National Center on Elder Abuse (n.d.) What is elder abuse? Retrieved from http://www.ncea.aoa.gov/faq/index.aspx

***Physical Abuse**:* the use of physical force that may result in bodily injury, physical pain, or impairment. Physical abuse may include but is not limited to such acts of violence as striking (with or without an object), hitting, beating, pushing, shoving, shaking, slapping, kicking, pinching, and burning. In addition, inappropriate use of drugs and physical restraints, force-feeding, and physical punishment of any kind also are examples of physical abuse.

***Neglect**:* the refusal or failure to fulfill any part of a person's obligations or duties to an elder. Neglect may also include failure of a person who has fiduciary responsibilities to provide care for an elder (e.g., pay for necessary home care services) or the failure on the part of an in-home service provider to provide necessary care. Neglect typically means the refusal or failure to provide an elderly person with such life necessities as food, water, clothing, shelter, personal hygiene, medicine, comfort, personal safety, and other essentials included in an implied or agreed-upon responsibility to an elder.

***Abandonment**:* the desertion of an elderly person by an individual who has assumed responsibility for providing care for an elder, or by a person with physical custody of an elder.

***Financial or material exploitation**:* the illegal or improper use of an elder's funds, property, or assets. Examples include, but are not limited to, cashing an elderly person's checks without authorization or permission; forging an older person's signature; misusing or stealing an older person's money or possessions; coercing or deceiving an older person into signing any document (e.g., contracts or will); and the improper use of conservatorship, guardianship, or power of attorney.

Aggregate Data: Data combined from several measurements. This summary data is 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 PO would be the total number of participant deaths from all causes during the specified three month period.

Adverse Drug Reaction: Any unintended effect on the body as a result of the use of therapeutic drugs, drugs of abuse, or the interaction of two or more pharmacologically active agents. 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. The Food and Drug Administration (FDA) maintains a drug safety database containing reports of serious adverse drug reactions entitled MedWatch. A serious adverse drug reaction will be reported as Level II incident when the patient outcome meets FDA guideline for reporting a serious adverse event under the FDA's MedWatch program. More information regarding MedWatch reporting can be found on the FDA's website at **http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm.**
CMS advises POs to monitor this database because it provides important and timely medical product information including information on prescription and over-the-counter drugs, biologics, medical devices, and special nutritional products.

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: The 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.

Level II Reporting Thresholds are defined as unexpected participant deaths as 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). POs having difficulty determining whether a death requires Level II Reporting should consult CMS by sending an email to pace@cms.hhs.gov.

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

Elopement: Elopement of a PACE participant occurs when a participant with medically documented cognitive deficits wanders away or leaves a PACE-sponsored setting without authorization and presents a threat of safety to self and others.

CMS acknowledges the right of a PACE participant to leave the PACE center at will when mentally capable to do so. Therefore, the term elopement for the purposes of Level II 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.

Equipment or Device Related Occurrence: The failure of medical equipment or device to perform in accordance to manufactures specifications or failure to operate equipment as intended by the manufacturer. Common causes of medical equipment or device failure are lack of knowledge regarding the appropriate operation of equipment or device, instructions/labeling/packaging errors, equipment or devices defects, software defects, inappropriate interactions with other devices while in use, failure to conduct equipment or device safety checks, failure to service equipment or devices as instructed by manufacturer, failure to report and remove defective equipment or devices from patient care areas in order to ensure they are not used until they are replaced or repaired that results in serious injury, serious illness, or death.

Fall: A sudden and unexpected change in position.

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.

Fire/Other Disasters: An environmental event at a PACE-sponsored setting that 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 PACE participants.

Improvement Activities: Activities undertaken by a PO in response to investigating unusual participant incidents or to correct program deficits. The PO follows its QI 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 or infectious agent impacting participants in a PACE Center, contracted facility, or other PACE housing arrangements resulting serious illness, hospitalization, or death.

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 PO or program.

The PO 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 PO enables CMS and SAA to collaborate in transmitting an accurate perspective of the PACE program.

Medication-related Occurrences: Mistakes or errors that occur when prescribing, dispensing, or administering a medication. POs 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.

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.

Motor Vehicle Accident (MVAs): Applies to MVAs in which PACE participants are transported in a vehicle owned, contracted, or operated by PACE personnel. Report 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, and excursions.

Participant: Individual enrolled in a PACE program.

Permanent Loss of Function: Any anatomical functional abnormality, or psychological decline as a result of a Level II event if permanent loss or change in function occurs at the time of the Level II event, and after reasonable medical treatment has been completed and participant has not regained previous level of function.

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).When determining the required level of reporting pressure ulcers, several points should be considered. Most pressure ulcers managed for nursing home residents heal within 60 days. Although not every pressure ulcer is preventable, the vast majority are.

- States have well defined reporting criteria and processes, though not usually through the SAA.
- The National Pressure Ulcer Advisory Panel has developed staging that CMS has adopted to guide reporting requirements for POs.
- Staging and reporting requirements are based on incidence, not outcome or effect on the participant.
- Pressure ulcers are not back staged as they heal.
- Provider assessment and documentation/reporting tools distinguish program-acquired from 'inherited' pressure ulcers.
- POs having difficulty determining whether a pressure ulcer requires Level II Reporting should consult CMS by sending an email to pace@cms.hhs.gov.

Report Stage III, IV, and unstageable pressure ulcers that develop while enrolled in PACE.

Stage I	Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching.
Stage II	Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled or sero-sanginous filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising*. This category should not be used to describe skin tears, tape burns, incontinence associated

	dermatitis, maceration or excoriation. Bruising indicates deep tissue injury.
Stage III	Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.
Stage IV	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present. Often includes undermining and tunneling.
Unstageable	Full thickness tissue loss in which actual depth of the ulcer is completely obscured by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.
Deep Tissue Injury	Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or *shear.* The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed

Restraint: PACE regulations 42CFR §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 POs 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.

Restraints can be either physical or chemical:

- ***Physical restraint***- any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that the individual cannot remove easily and which restricts freedom of movement or normal access to one's body. Includes but not limited to leg restraints, arm restraints, hand mitts, soft ties or vests, lap cushions, and lap trays the patient can't remove easily.
- ***Chemical restraint*** -any drug that is used for discipline or convenience and is not required to treat medical symptoms.

Root Cause Analysis: A structured process that uncovers the physical, human, and latent causes of any undesirable event in the work place.

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.

Appendix B: Quality Improvement (QI) Information

CMS and SAAs partner with POs to enhance internal quality assurance and risk management activities. Through the reporting requirements, CMS and the SAA monitor the POs quality of care and risk reduction efforts. Monitoring activities refer to both the submission of the monitoring data elements via the PACE monitoring module of the HPMS, and the reporting of events resulting in significant harm to participants, or negative national or regional notoriety related to the PACE program.

Appendix C: References

Agency for Healthcare Research and Quality http://www.ahrq.gov
- Clinical practice guidelines
- Preventing medical errors
- Quality care
- Safe care

Centers for Disease Control and Prevention http://www.cdc.gov
- Injury, violence and safety
- Older adults and seniors health issues
- Research publications

Centers for Medicare & Medicaid Services http://www.cms.gov
- Quality initiatives and research

PACE regulations (42 CFR 460) http://www.ecfr.gov

Food and Drug Administration http://www.fda.gov
- Drug safety
- Medical device and equipment safety
- MedWatch reporting

Institute of Medicine http://www.iom.edu
- Aging issues
- Healthcare and quality issues
- Research publications

The Joint Commission www.jointcommission.org
- Participant safety
- Root Cause Analysis process
- Sentinel event alert reports

National Pressure Ulcer Advisory Panel http://www.npuap.org
- Research and guidelines on pressure ulcer management

National Institute of Aging http://www.nia.nih.gov
- Research publications
- Safety issues

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/