PACE Quality Data Monitoring & Reporting Guidance

March 2021

This document provides an overview of the Programs of All Inclusive Care for the Elderly (PACE) quality monitoring and reporting requirements outlined in Title 42 of The Code of Federal Regulations (CFR), §§460.130(d), 460.200(b)(1), 460.200(c) and 460.202. Note that POs are also required to timely report certain unusual incidents to other Federal and State agencies consistent with applicable statutory or regulatory requirements (see 42 CFR §460.136(a)(5)). Specific reporting requirements and timeframes may be found on the respective Federal or State agency websites.

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 and concurrently to the Centers for Disease Control and Prevention (CDC), if required.

To be in compliance with the above-referenced regulatory requirements, PACE organizations (POs) must report both aggregate and individual PACE Quality Data to CMS. All PACE Quality Data must be reported in the PACE Quality Monitoring Module in the Health Plan Management System (HPMS). For information on how to enter PACE Quality Data, please see the HPMS PACE Quality Monitoring User Guide located in the PACE Quality Module in HPMS. For questions regarding HPMS, contact the HPMS helpdesk at hpms@cms.hhs.gov. For questions regarding HPMS access, contact the HPMS user access mailbox at hpms_access@cms.hhs.gov.

PACE Quality Data

There are two types of PACE Quality Data:

PACE Quality Data without Root Cause Analysis

This type of quality data relates to administrative processes, such as appeals, grievances, enrollments, disenrollments, enrollment denials, etc., and does not require a root cause analysis (RCA). Other areas reported under this category include utilization of services, for example, emergency care, hospital admissions, and preventive care, e.g., immunizations. The frequency for reporting PACE Quality Data without RCA is quarterly. CMS provides POs with a 45 calendar day reporting grace period at the end of each quarter. For example, for quarter 1 which ends on March 31st, all PACE Quality Data must be reported by the deadline of May 15th. POs are not precluded from submitting PACE Quality Data prior to the end of the quarter.

PACE Quality Data with Root Cause Analysis

This type of quality data relates to unusual incidents that result in serious adverse outcomes, or negative national or regional notoriety related to PACE, and requires an RCA for quality improvement purposes and to mitigate further and/or future incidence. Reportable incidents include, but are not limited to, unexpected deaths, infectious disease outbreaks, falls with injury and/or serious traumatic injuries while enrolled in the PACE program. The frequency for reporting PACE Quality Data with RCA is quarterly. CMS provides POs with a 45 calendar day reporting grace period at the end of each quarter. For example, for quarter 1 which ends on March 31st, all PACE Quality Data must be reported by the deadline of May 15th. POs are not precluded from submitting PACE Quality Data prior to the end of the quarter.

POs must also initiate an RCA investigation internally within three working days of identifying the incident. The analysis must be completed and documented in HPMS within the 45 day grace period at the end of each quarter. POs are required to document all RCA information in the fields provided in HPMS, as well as indicate what the participant's current status is, both prior to and at the conclusion of the RCA investigation.

For PACE quality incidents that require an RCA, CMS will consider the data submission complete once the RCA data has been entered in HPMS. If an RCA cannot be completed and entered into HPMS within the 45 day grace period, the PO may request an extension in HPMS. Please see the HPMS PACE Quality Monitoring User Guide for additional information and instructions on requesting an extension.

Note: Supporting documentation for an RCA may be submitted in HPMS through the upload document feature, however, CMS does not require the submission of supporting documentation into HPMS and expects that this will only be done on a voluntary basis, and only in extraordinary or unusual circumstances. Some examples of supporting documentation may include, but are not limited to: police and/or coroner reports, complex adverse outcomes, motor vehicle accidents involving serious injury and/or death, etc.

CMS expects POs to discuss PACE Quality Data and any RCA findings with their CMS Account Manager (AM) on an ongoing basis. The AM may request a more detailed discussion with the PO regarding a specific PACE quality incident/event, and the RCA that was conducted in response. To facilitate the discussion, the PO should prepare a case presentation that includes the following information:

- Enrollment date
- Participant's current status
- Significant diagnoses
- Summary of the care history
- Summary of the event
- Immediate actions taken
- IDT team's main concerns related to participant prior to event
- Precipitating/contributing factors
- Participant's involvement/actions surrounding the event
- Participant's degree of involvement in PACE program
- Working relationship with contracted facility, contracted services (if applicable)
- Compliance with PO's established policies and procedures
- Identification of risk points or policy deficiencies and their potential contribution to the event
- Actions taken by the PO to reduce future risk, i.e., quality improvement projects, policy revision, staff training, participant education, revision of procedures, alteration in staffing levels, etc.

It is important that POs document all participant related events, such as falls, burns, adverse outcomes, etc. in the medical record, including those that result in injury, require treatment, a change in the care plan, or loss of function. Documentation should include details of the incident as well as assessments, diagnoses, consultations, changes to the plan of care, follow-up, and progress notes, as appropriate/required. The PO does not need to include details in the medical record that relate to the investigation of the incident/event (e.g., contributing factors, inconsistent care that conflicted with policy, quality concerns, etc.). Instead, this documentation should be kept separately in a Quality Assurance file.

POs should regularly monitor their PACE Quality Data for Quality Improvement (QI) purposes using a standardized methodology (e.g., Plan, Do, Study, Act, known as PDSA) to:

- Identify, track and trend opportunities and/or areas in need of improvement;
- Develop and implement a plan(s) of action to improve or maintain quality of care and services;
- Institute QI-driven change in policies, procedures, systems, or training as appropriate;
- Evaluate the effectiveness of interventions;
- Monitor for sustained improvement;
- Report and discuss findings with oversight committees including the PO's governing body; and
- Document evidence of a performance improvement activity(s) for review by the PACE organization, CMS, and the State Administering Agency (SAA).

PACE Quality Data Reporting Requirements and Thresholds

Appendix A provides the PACE Quality Data reporting requirements and thresholds. For additional information, please see Appendix B, Defining Terms. For questions concerning PACE Quality Data reporting, POs should contact their CMS AM and/or the PACE portal at https://pace.lmi.org.

Appendix A: PACE Quality Data Reporting Requirements and Thresholds

Incident	Reporting Thresholds	Root Cause Analysis Required? Yes/No
Abuse: Categories of abuse include: Abandonment, Emotional/Psychological Abuse, Financial or Material Exploitation, Neglect, Physical Abuse, Self-Neglect and Sexual Abuse.	• All abuse incidents **confirmed** by state authorities are reported to CMS. • Please note, all suspected and allegations of abuse must be reported to appropriate state authorities, but only reported to CMS as a quality incident if the abuse is *confirmed*.	Yes
Appeal: An appeal is a participant's or caregiver's action taken with respect to the PO's non-coverage of, or nonpayment for a service, including denials, reductions, or termination of services.	• Appeals are entered into HPMS once the appeal has been resolved or denied.	No
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.	• Resulted in death; or • Resulted in injury requiring hospitalization (admission or observation stay more than 23 hours) related directly to the adverse drug reaction; or any adverse drug reaction that meets the Food and Drug Administration (FDA) guidelines for reporting under the FDA's MedWatch program. More information regarding 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.	Yes

Incident	Reporting Thresholds	Root Cause Analysis Required? Yes/No
Adverse Outcome: A serious, undesirable, and unexpected outcome resulting from the participant's care or treatment.	• Resulted in death; • Resulted in injury requiring hospitalization (admission or observation stay more than 23 hours) related directly to the adverse outcome; or resulted in a fracture requiring surgical interventions.	Yes
Burns 2nd Degree or Higher: An injury to tissue caused by heat, friction, electricity, radiation, or chemicals that results in a 2nd or 3rd degree burn(s).	• Burn(s) 2nd degree or higher; and/or • Required the following: o Treatment by a physician or primary care provider, and/or o An emergency room visit, or required hospitalization (admission or observation stay more than 23 hours) related directly to the burn.	Yes
Elopement: A participant with cognitive impairment, wanders away or leaves an area without supervision or authorization and presents a safety threat to the participant and/or others.	• All elopements.	Yes
Emergency Room and/or Urgent Care Visit(s): Is any unscheduled care provided in an emergency room or urgent care center.	• Any instance in which a PACE participant receives unscheduled care provided in a hospital emergency room or an urgent care center. • Data includes whether or not the participant was admitted to the hospital (yes/no) or observation stay, and • Has this participant had repeat ER visits (i.e. a return visit to an ER or urgent care setting within the reporting period)?	No

Incident	Reporting Thresholds	Root Cause Analysis Required? Yes/No
Enrollment Data: Enrollment data is the total number of participants who were enrolled in the PACE organization, as well as prospective enrollee denials, during the reporting quarter.	• Data is collected at an organizational level until the last day of the quarter and includes: • Total Enrollments; • Total New Enrollments; • Enrollment Denials (prospective enrollees) including the denial date and denial reason; • Total Disenrollments (does not include deaths); and • Total Deaths. Note: Participant deaths should be reported as a "death" and not as a "disenrollment" from PACE.	No
Equipment Related Occurrences: Failure of medical equipment or device to perform in accordance with manufacturers' specifications, or failure to operate equipment as intended by the manufacturer.	• Resulted in death; • Resulted in injury requiring hospitalization (admission or observation stay more than 23 hours) related directly to the equipment-related occurrence; or An equipment related occurrence that directly affected the participants' safety that meets the FDA guideline for reporting under the FDA's MedWatch program. More information regarding reporting can be found on the FDA's website: http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm.	Yes
Falls with Injury: A sudden, unintentional, descent of the body to either the floor/ground, or another object.	• Resulted in death; • Resulted in a fracture; or Resulted in injury requiring hospitalization (admission or observation stay more than 23 hours) related directly to the fall.	Yes

Incident	Reporting Thresholds	Root Cause Analysis Required? Yes/No
Falls without Injury: A sudden, unintentional, descent of the body to the floor/ground, or another object.	• Any fall that does not result in death, a fracture, or an injury requiring hospitalization related directly to the fall.	No
Fires/Other Disasters: Environmental event at a PACE-sponsored setting that requires the evacuation of, or, an unanticipated closure of a PACE center.	• Resulted in death; • Resulted in injury requiring hospitalization (admission or observation stay more than 23 hours) related directly to the fire or disaster; or • Resulted in the inability to provide care/disruption of care.	Yes
Foodborne Outbreak: A foodborne disease outbreak is defined as an incident in which three or more persons experience a similar illness resulting from the ingestion of a common food.	• Resulted in death; or • All foodborne outbreaks that meet the threshold of three or more cases of persons exhibiting related symptoms resulting from intake of a similar food source must be reported to CMS and the State public health authority. Some situations may require additional reporting to the CDC.	Yes
Grievances: A grievance is defined as a complaint, either written or oral, expressing dissatisfaction with service delivery or quality of care.	• Grievances are entered under one of two categories: • Resolved; or • Alternative Solution, which means that the PO has chosen an alternative option to address the grievance(s) safely and appropriately. Note: Some grievances may not be resolved to the participants/caregiver satisfaction, however, CMS expects that all grievances will reach a resolution.	No

Incident	Reporting Thresholds	Root Cause Analysis Required? Yes/No
Immunizations: Pneumococcal and influenza immunizations are reported for all participants enrolled during the reporting period. CMS expect POs to immunize participants according to current CDC guidelines. ***Pneumococcal****:* *https://www.cdc.gov/vaccines/vpd/pneumo/index.html* ***Influenza:*** *http://www.cdc.gov/vaccines/vpd-vac/flu/default.htm*.	For each participant, the PO provides the following information regarding vaccinations: • All participants enrolled during the reporting period (including new, current, disenrolled and deceased participants); • The total eligible to receive immunization; • The number of vaccines administered by the PO to eligible participants; • The total number eligible participants who did not receive the Pneumococcal/Influenza for the following reasons: o Medically contraindicated; o Prior immunization; o Refused; o Vaccine unavailable; or o Missed opportunity (vaccine available but was not administered); and • The number of participants who received the vaccine and reported or had a reaction.	No
Infectious Disease Outbreak: Three or more cases of the same illness resulting from the same source or infectious agent impacting PACE participants.	• Resulted in death; or • All incidents that are reportable to the respective State or County public health authority; or • Have three or more cases and are linked to the same infectious agent within the same time frame. The time frame is dependent on the infectious agent. Note: Some situations may require additional reporting to the CDC.	Yes

Incident	Reporting Thresholds	Root Cause Analysis Required? Yes/No
Media Related Event: Any reporting through local, state, regional or national media outlets (print, broadcast, web-based, radio, etc.) that may potentially or actually presents a harmful characterization of a PO or the National PACE program.	• Any report of which the PO is aware through local, state, regional, or national media outlets (print, television or radio broadcast, web-based, 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).	Yes
Medication Administration Errors Without an Adverse Effect: Medication errors that occur in violation of a physician's order that **did not** result in death, injury or adverse outcome requiring hospitalization (admission or observation stay more than 23 hours) related directly to the medication related occurrence.	• Any medication error including: o Prescribing the wrong medication to a participant; o Dispensing the wrong medication to a participant; o Administration of the wrong medication to a participant; o Administration of medication via an incorrect route; o Administration of medication at the incorrect time; or o Administration of an incorrect dosage of medication.	No

Incident	Reporting Thresholds	Root Cause Analysis Required? Yes/No
Medication Related Occurrence: Medication errors that occur in violation of a physician's order that **did** result in death, injury or adverse outcome requiring hospitalization (admission or observation stay more than 23 hours) related directly to the medication related occurrence.	• Any medication error including: o Prescribing the wrong medication to a participant; o Dispensing the wrong medication to a participant; o Administration of the wrong medication to a participant; o Administration of medication via an incorrect route; o Administration of medication at the incorrect time; or o Administration of an incorrect dosage of medication.	Yes
Motor Vehicle Accident: When a PACE participant is involved in an accident while in a vehicle that is operated by PACE Staff and or PACE contractors.	• Resulted in death; • Resulted in injury requiring hospitalization (admission or observation stay more than 23 hours) related directly to motor vehicle accident; or • Resulted in injury requiring emergency room intervention without hospitalization (i.e. evaluation, suturing, splinting, or other treatment).	Yes
Pressure Injury: A pressure injury that is acquired while enrolled in PACE.	• Stage 3; • Stage 4; or • Unstageable For more information, visit the National Pressure Injury Advisory Panel website at https://npiap.com.	Yes
Restraint Use: The use of a physical or chemical restraint on a PACE participant.	• Resulted in death; or Resulted in injury requiring hospitalization (admission or observation stay more than 23 hours) related directly to restraint use.	Yes

Incident	Reporting Thresholds	Root Cause Analysis Required? Yes/No
Suicide Attempt/ Suicide: An individual deliberately initiates a behavior that will cause self-harm.	• Suicide attempt; or • Resulted in death.	Yes
Unexpected Death: Irreversible cessation of circulatory and respiratory functions, or irreversible cessation of all functions of the entire brain that was unanticipated and/or unexpected in nature.	• Homicide (known or suspected); or • Unexpected death with a coroner investigation.	Yes

Appendix B: Defining Terms

Abuse: According to the National Center on Elder Abuse (NCEA), the following types of abuse are commonly accepted as the major categories of elder mistreatment:

- Physical Abuse: Inflicting or threatening to inflict, the use of physical force that may result in bodily injury, physical pain or impairment;
- Emotional or Psychological Abuse: The infliction of anguish, pain, or distress through verbal or nonverbal acts;
- Sexual Abuse: Non-consensual sexual contact of any kind with an elderly person;
- Financial or Material Exploitation: The illegal or improper use of an elder's funds, property, or assets;
- Neglect: The refusal or failure to fulfill any part of a person's obligations or duties to an elder;
- Abandonment: The desertion of an elderly by an individual who has assumed responsibility for providing care for an elder, or by a person with physical custody of an elder;
- Self-Neglect: Characterized as the behavior of an elderly person that threatens his/her own health or safety.

For more information on elder abuse, visit the NCEA website at https://ncea.acl.gov/.

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 FDA maintains a drug safety database containing reports of serious adverse drug reactions entitled MedWatch. A serious adverse drug reaction will be reported 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 the FDA MedWatch in order to keep up to date with important 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 resulting from care or treatment.

Appeal: An appeal is a participant's action taken with respect to the PO's non-coverage of, or nonpayment for, a service including denials, reductions, or termination of services.

Burn: An injury to tissue 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: 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. For reporting purposes, there are two categories of deaths, these include; 1. **Deaths** that are expected or anticipated, and reported as part of enrollment data, and 2. **Unexpected Deaths**, which are a result

of a homicide and/or otherwise unanticipated in nature and have or will undergo an active coroner investigation.

Elopement: Occurs when a participant with cognitive impairment, wanders away or leaves an area without supervision or authorization and presents a safety threat to the participant and/or others.

CMS acknowledges the right of a PACE participant to leave the PACE center at will when mentally capable of doing so. Therefore, for reporting purposes, the term elopement is limited to participants whose medical condition(s) involves cognitive deficits and/or impaired judgment, or to those deemed legally incapable of making their own decisions about complying with documented treatment plans.

Emergency Room Visit: Any instance in which a PACE participant receives unscheduled care provided in a hospital emergency room or an urgent care center.

Enrollment Data: The total number of participants who were enrolled in the PACE organization during the reporting quarter, including new enrollments and prospective enrollee denials, total disenrollments, and total deaths. For purposes of PACE Quality Data reporting, a participant death should be reported as a "death" and not as a "disenrollment" from PACE.

Equipment or Device Related Occurrence: The failure of medical equipment or device to perform in accordance with manufacture's specifications or failure to operate equipment as intended by the manufacturer. Common causes of medical equipment or device failure include: 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 to ensure they are not used until they are replaced or repaired that results in serious injury, serious illness, or death.

Fall: A sudden, unintentional, descent of the body to either the floor/ground, or another object, For reporting purposes, there are two categories of falls, these include; 1. **Falls without Injury**, and 2. **Falls with Injury** that result in death, fracture, and/or an injury requiring hospitalization (admission or observation stay more than 23 hours) related directly to the fall.

Fire/Other Disasters: An environmental event at a PACE-sponsored setting that requires the evacuation of, or, an unanticipated closure of a PACE center, and usually results in the inability to provide care or causes a disruption in care. These events include but are not limited to: Blizzard, Earthquake, Fire, Heavy Rain/Flood, Hurricane, Ice Storm, Power Outage, Tornado and/or Other Type.

Foodborne Outbreak: A foodborne disease outbreak is defined as an incident in which three or more persons experience a similar illness resulting from the ingestion of a common food.

Immunizations: Refers to the reporting of pneumococcal and influenza immunization data. Immunization data is reported for all participants enrolled during the reporting period. Pneumococcal immunizations are reported on a quarterly basis. The data collection period for influenza immunizations begins October 1 and ends March 31st of the following calendar year, and reported at the end of quarter 1.

Infectious Disease Outbreak: Three or more cases of the same illness resulting from the same source or infectious agent impacting PACE participants. POs are required to report an infectious disease outbreak if one or more of the criteria below is met:

- Resulted in death; or
- All incidents that are reportable to the respective State or County public health authority; or
- Have three or more cases and are linked to the same infectious agent within the same time frame. The time frame is dependent on the infectious agent.

Media Related Incident: Any reporting through local, state, regional or national media outlets (print, broadcast, web-based, radio, etc.) that may potentially or actually presents a harmful characterization of a PO or the National PACE program. The PO must notify CMS and the SAA when knowledge of adverse publicity 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: Medication errors that occur in violation of a physician's order and result in death, injury or adverse outcome requiring hospitalization (admission or observation stay more than 23 hours) related directly to the medication related occurrence.

POs must 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. 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, and ambiguities in product names or directions for use.

Medication Administration Errors without an Adverse Effect: Medication errors that occur in violation of a physician's order that **do not** result in death, injury or adverse outcome requiring hospitalization (admission or observation stay more than 23 hours) related directly to the medication related occurrence.

Motor Vehicle Accident (MVA): Applies when a PACE participant is involved in an accident while in a vehicle that is operated by PACE Staff and/or PACE contractors. POs must report a vehicle collision that occurs while transporting PACE participants to and/or from a PACE sponsored activity. PACE sponsored activities can include but are not limited to travel to and/or from the PACE Center, community-based appointments, visits, excursions, etc.

Participant: Any individual enrolled in a PACE program.

Pressure Injury: According to the National Pressure Injury Advisory Panel (NPIAP), a pressure injury is localized damage to the skin and underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue.

PACE organizations must report stage 3, 4, and unstageable pressure injuries that develop while enrolled in PACE. For more information on pressure injuries, please visit the NPIAP website at https://npiap.com/.

Quality Improvement Activities: Any activity undertaken by a PO to improve processes, the delivery of care and services, or participant outcomes. Quality improvement activities may be targeted at the organizational, provider team, or participant level.

Examples include:

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

Reporting Quarter(s):

Quarters	Quarter Begins	Quarter Ends	Last Day to Enter Quarterly Data
1	January 1st	March 31st	May 15th
2	April 1st	June 30th	August 15th
3	July 1st	September 30th	November 15th
4	October 1st	December 31st	February 15th

Restraint: PACE regulation 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 for achieving a safe environment or safe participant behavior, PACE regulations do permit the limited use of these restraint types:

- ***Physical restraint***--any manual method or physical/mechanical device, material, or equipment attached or adjacent to the participant's body that cannot easily be removed and restricts freedom of movement or normal access to one's body. Examples include but are not limited to leg restraints, arm restraints, hand mitts, soft ties, vests, lap cushions, and lap trays that can't easily be removed.
- ***Chemical restraint***--any 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.

Root Cause Analysis: A multi-disciplinary process of study or analysis that uses a detailed and structured process to examine factors contributing to a specific outcome (e.g., an adverse event).

Suicide Attempt: An act with a non-fatal outcome in which a participant 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 C: Resources

Resources	Webpage
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 • Immunizations • Infectious disease and foodborne outbreaks • Injury, violence and safety • Older adults and seniors health issues	**http://www.cdc.gov**
Centers for Medicare & Medicaid Services • Quality initiatives and research	**http://www.cms.gov**
PACE Regulations (42 CFR Part 460)	**http://www.ecfr.gov**
Food and Drug Administration • Drug safety • Medical device and equipment safety • MedWatch reporting	**http://www.fda.gov**
ICD 10 CODES	**https://www.cms.gov/Medicare/Coding/ICD10/index**
The Joint Commission	**www.jointcommission.org**
National Academies of Sciences, Engineering and Medicine (formerly the IOM) • Aging issues • Health care and quality issues • Research publications	**https://www.nap.edu/**
National Pressure Injury Advisory Panel • Research and guidelines on pressure injury management	**https://npiap.com**
National Institute of Aging • Research publications • Safety issues	**http://www.nia.nih.gov**
Institute for Safe Medication Practices	**http://www.ismp.org/**
National Association of Boards of Pharmacy	**http://www.nabp.net/**
American Society of Consultant Pharmacists	**http://www.ascp.com/**

PRA Disclosure Statement

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