PACE Level II Reporting Guidance

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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 & Medicaid Services (CMS) and State administering agencies (SAAs) for their use in monitoring POs' performance.

Level II Reporting Requirements apply specifically to unusual incidents that result in serious adverse participant outcomes, or negative media coverage related to the PACE program. POs are required to report incidents within 3 working days to **https://DMAO.LMI.org** with a copy to the Regional Office (RO) and the SAA. **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.

Level II Incidents and Reporting Thresholds

Table 1, **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. In addition, after a Level II incident occurs, the PO must immediately correct any identified problem that directly or potentially threatens the health and safety of a PACE participant. See 42 CFR §460.136(a)(5). Please see pages 8-9 for information on conducting a Root Cause Analysis.

Level II Incidents and Reporting Thresholds ***(See Appendix A for definitions of terms)***	
Incident	**Level II Reporting Thresholds**
Abuse: including self-inflicted and physical, financial, verbal, emotional, psychological, or sexual.	All suspected and allegations of abuse must be reported to appropriate state authorities. All abuse incidents confirmed by state authorities are reported to CMS as a Level II.
Adverse Drug Reactions: 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 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.**
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.
Burns: an injury to tissue caused by heat, friction, electricity, radiation, or chemicals.	Burn(s) 2nd or 3rd degree; All repeat burn(s) (3 or more in 90 days) burn incidents by the same participant; or Resulted in providing treatment greater than first aid or requiring hospitalization (admission or observation stay more than 23 hours) related directly to the burn.
Deaths: irreversible cessation of circulatory and respiratory functions, or irreversible cessation of all functions of the entire brain.	Homicide (known or suspected); or Unexpected Death (provide an active coroner investigation when submitting Root Cause Analysis (RCA) to CMS).
Elopement: a participant wanders away or leaves a PACE-sponsored setting, participant's home, Skilled Nursing Facility, or Assisted Living Facility without notification.	All elopements.
Equipment-Related Occurrences: failure of medical equipment or device to perform in accordance to 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 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.**

Level II Incidents and Reporting Thresholds ***(See Appendix A for definitions of terms)***	
Incident	**Level II Reporting Thresholds**
Falls: sudden, uncontrolled, unintentional, non-purposeful downward displacement of the body to the floor/ground, or hitting another object.	Resulted in death; Resulted in a fracture; or Resulted in injury requiring hospitalization related directly to the fall.
Fires/Other Disasters: environmental event at a PACE-sponsored setting that requires evacuation or unanticipated or sudden closure of a PO.	Resulted in death; Resulted in injury requiring hospitalization (admission or observation stay more than 23 hours) related directly to the fire or disaster; Resulted in inability to provide care/disruption of care; or Resulted in a loss of safe housing for PACE participants.
Food-borne outbreak: three or more cases get the same symptoms from the same contaminated food or drink.	Resulted in death; or All food-borne outbreaks that meet the threshold of three or more cases of persons exhibiting related symptoms resulting from intake of a similar food source may be reportable to the State public health authority either prior to or after the completion of a RCA. Some situations may require additional reporting to the Centers for Disease Control and Prevention (CDC).
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.	Resulted in death; or 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 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. If so, POs report the threshold that is the primary cause of death.
Media-related Event: 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.	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).
Medication-related Occurrences: mistakes or errors that occur when prescribing, dispensing, or administering a medication.	Resulted in death; Resulted in injury requiring hospitalization (admission or observation stay more than 23 hours) related directly to the medication-related occurrence; or Resulted in a near-death event, e.g., anaphylaxis, cardiac arrest.

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Level II Incidents and Reporting Thresholds *(See Appendix A for definitions of terms)*	
Incident	**Level II Reporting Thresholds**
Motor Vehicle Accidents: When a PACE participant is involved in an accident involving a vehicle operated by PACE Staff and or PACE contracted/owned transportation.	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 Department intervention without hospitalization, such as evaluation, suturing, splinting, or other treatment.
Pressure Ulcer: acquired while enrolled in PACE.	Stage III; Stage IV; or Unstageable.
Restraint Use: physical or chemical.	Resulted in death; or Resulted in injury requiring hospitalization (admission or observation stay more than 23 hours) related directly to restraint use.
Suicide and Suicide Attempts: an individual deliberately initiates a behavior that will cause self-harm.	Resulted in death; or Suicide attempts.

Additional Reporting to Other Federal and State Health Authorities

In addition to required CMS and SAA reporting, POs are also 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. 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 required actions within the prescribed timeframe to comply with applicable statutory or regulatory requirements (see 42 CFR §460.136(a)(5)). 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. Notify CMS via **https://DMAO.LMI.org** and copy the RO AM and SAA within three working days of incident occurrence.

Content of initial notification:

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

Illustrative Example:

a) Issue: PACE Level II Report
b) Fall on March 13, 2014
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

***Note**: This example is for illustrative purposes only.*

CMS may request that the PO conduct a full RCA. If CMS determines that a RCA is needed, CMS will send a response to the PO to initiate an internal investigation. The email from CMS will include a CMS reference 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, the PO should consults with their CMS Account Manager first before submitting their question via **https://DMAO.LMI.org**. The PO's contact with CMS must be made by the next business day after a determination that Level II reporting may be required.

All participant-specific events resulting in injury, requiring treatment, a change in the plan of care, or loss of function must be documented in the medical record.

2) Conduct Root Cause Analysis. A PACE organization must initiate an investigation within three working days of reporting the incident to CMS and the SAA. The analysis must be concluded within 45 calendar days of reporting the incident. If the analysis cannot be completed within 45 calendar days, the PO must notify CMS via **https://DMAO.LMI.org** with a copy to the RO AM and the SAA. The notification must describe the circumstances that prevented completion of the investigation within the 45 calendar 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 RCA.

As discussed above, it is important that a PACE organization document all participant-specific events in the medical record, especially if they result in injury, require treatment, a change in the care plan, or loss of function. Documentation should include a statement of the event, an assessment, a diagnosis (if appropriate), policy changes, 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 https://DMAO.LMI.org with a copy to the RO AM and the SAA of the completed analysis.** The RO AM may schedule a conference call to discuss the PO's internal investigation, subject to the availability of key individuals (CMS AM, CMS clinician, PO, and SAA) from all entities.

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

When the PO has completed its RCA, the PO must notify CMS via **https://DMAO.LMI.org** 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:

a) Reference number
b) Age and gender
c) Enrollment date
d) Participant's current status
e) Significant diagnoses
f) Summary of the care history
g) Summary of the event
h) Immediate actions taken
i) IDT team's main concerns related to participant prior to event
j) Precipitating/contributing factors
k) Participant's involvement/actions surrounding the event
l) Participant's degree of involvement in PACE program
m) Working relationship with contracted facility, contracted services (if applicable)
n) Compliance with PO's established policies and procedures
o) Identification of risk points or policy deficiencies and their potential contribution to the event
p) 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 sent to https://DMAO.LMI.org as an unencrypted attachment prior to the call.

Process for Conducting Root Cause Analysis

The PO must conduct a RCA, within three working days of reporting the incident, 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, or multiple fail-safe measures are required as part of the PO's quality assessment and performance improvement (42 CFR §460.130, §460. 132, §460134 and §460.136).

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 **https://DMAO.LMI.org** and a copy to the RO AM and SAA. The submission should include the reference number and the 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 POs in determining which 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 three categories of elder abuse:

- *Domestic Elder Abuse*: generally refers to any of several forms of maltreatment of an elderly adult 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*: generally refers to any of the above-mentioned forms of abuse that occur in residential facilities for elderly persons (e.g., nursing homes, foster homes, group homes, 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- or gives away, sells their medication and or replace their medication with illegal medications), 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 the elder person 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 an elderly person, (e.g. such as telling a elder he/she 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 elderly 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 elderly 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 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 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.

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.

Note: For all participant deaths, POs must have an internal process to capture data on each participant death and report this information in HPMS.

Elopement: Occurs when a participant wanders away or leaves a PACE-sponsored setting, a participant's home, a Skilled Nursing Facility, and Assisted living Facility 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 of doing so. Therefore, the term elopement for the purposes of Level II Reporting is limited to participants whose medical condition resulting 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 manufacture's 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; as well as 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, uncontrolled, unintentional, non-purposeful downward displacement of the body to the floor/ground, or hitting another object. 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 unanticipated or sudden closure of a PO resulting in the inability to provide care/disruption in care (i.e. tornado, bombing, earthquake), or results in a loss of safe housing for PACE participants.

Food-borne outbreak: Three or more people get the same illness from the same contaminated food or drink.

Improvement Activities: Activities undertaken by a PO in response to investigating unusual participant incidents or to correct program deficits. The PO follows its quality improvement 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; or
- 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 arrangement 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 the PACE 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. 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, contracted/owned, 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.

Pressure Ulcer: According to the National Pressure Ulcer Advisory Panel (NPUAP) a pressure ulcer is a 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. When determining the required level of reporting pressure ulcers, PACE organizations should consider that most pressure ulcers managed for nursing home residents heal within 60 days. The vast majority of pressure ulcers are preventable. POs having difficulty determining whether a pressure ulcer requires Level II reporting should consult with their CMS account manager and or submit their inquiry to **https://DMAO.LMI.org.** PACE organizations should report stage III, IV, and unstageable pressure ulcers that develop while enrolled in PACE. Please refer to for the NPUAP for stage definitions: *www.npuap.org.*

Restraint: PACE regulations 42CFR §460.114 stipulate 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 participant 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 multi-disciplinary process of study or analysis that uses a detailed, 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 B: 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
- Infectious disease and foodborne outbreaks
- 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 Database of Nursing Quality Indicators http://www.nursingquality.org/
- Quality measures and indicators
- Research-based practice

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/