Don’t Let IJ’s Keep You From Soaring
Session W29
Wednesday April 29, 2015
2:30-5:30 pm

Presented By:
• Mary Burkart, RN
  - nurses@icppharm.com
• Erin McClure, BSN, RN, WCC
  - emcclure@icppharm.com
• Institutional Care Pharmacy, Tiffin OH

Program Purpose
• Take **flight** into this 3-hour educational session focusing on survey preparedness. **Plummet** into the depths of Ohio’s top IJ citations & causative factors. **Ascend** into preventive strategies, enabling your care community to **soar** to new heights!
Objectives

• Analyze recent IJ citations
• Identify behaviors that may put a facility at risk for IJ citation
• Discuss preventive strategies to avoid IJ citations

What is an Immediate Jeopardy?

A situation in which the facility's noncompliance with one or more requirements of participation:
• Has allowed, caused, or resulted in (or is likely to allow, cause, or result in) serious injury, harm, impairment, or death to a resident; and
• Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Why do IJ's Occur?

• Facility's failure to obtain and implement medical orders related to life-sustaining treatments
• Noncompliance could place residents into a situation with potential to sustain serious harm, injury or death
• The resident experienced actual psychological harm
Terminology

- Harm
- Actual
- Potential
- Immediacy
- Culpability

Scope of the Deficiency

<table>
<thead>
<tr>
<th>Severity of the Deficiency</th>
<th>Isolated</th>
<th>Pattern</th>
<th>Widespread</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate jeopardy to resident health or safety (Level 4)</td>
<td>J</td>
<td>K</td>
<td>L</td>
</tr>
<tr>
<td>Actual harm that is not immediate jeopardy (Level 3)</td>
<td>G</td>
<td>H</td>
<td>I</td>
</tr>
<tr>
<td>No actual harm with potential for more than minimal harm that is not immediate jeopardy (Level 2)</td>
<td>D</td>
<td>E</td>
<td>F</td>
</tr>
<tr>
<td>No actual harm with potential for minimal harm (Level 1)</td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
</tbody>
</table>

4th Quarter 2014 IJ Citations

- F309*
- F323, F325, F326*
- F223*
- F221*
- F314*
- F329
- F441

*Recurrent IJ citation in 2014
Secondary Citations

• F224
• F226
• F157
• F222
• F272
• F279
• F280
• F281
• F385

• F501
• F201
• F332/333
• F428
• F508
• F325
• F242
• F365
• F353

F-323 Accidents & Hazards

• Elopement
• Suicide Attempt
• Equipment
• Falls
• Choking

Staff Behaviors

• What is going on in your building??
  • Who knows the information?
  • What’s done with it?
  • Delays in reporting
  • Delays in investigating
More Behaviors
• Lack of assessment (initial & follow-up)
• Lack of knowledge/education
• Lack of follow-through

Preventive Strategies-Facility
• P/P
• Investigations
• Care Conferences
• Family meetings
• Res/Family council
• Tools-INTERACT, MDS, ‘Falling Stars’
• QAPI

Preventive Strategies-Physician
• Documentation
• Accessibility
Preventive Strategies-Nurses
- Clinical skills
- Competencies
- Communication skills

Preventive Strategies-STNA
- Competencies
- Communication skills

Preventive Strategies-Others
- Communication skills
F309 Pt. Well-Being

- CPR
- Choking
- Resident rights
- Dysphagia

Ohio Nursing Law

- RN  OAC 4723-4-07
- LPN  OAC 4723-4-08
- ORC 4723.36

Staff Behaviors

- Who knows the information?
- What's done with the information?
- Delays in reporting
Professional Guidelines

- CMS
- AHA
- Communication

Preventive Strategies-Facility

- P&P
- Advanced directives
- Care plans
- Mock Codes?

Preventive Strategies-Physician

- Communication- “the talk”
- Comprehensive assessment
Preventive Strategies - Nurses

- Immediate needs
  - Not the time to question code status

Preventive Strategies - STNA’s

- Are STNA’s aware of all altered texture diets?
- Are your STNA’s CPR certified?
- Do they know the Heimlich (Abd. Thrusts)?
- Do you use Feeding Assistants?

Preventive Strategies - Others

- When to get help
F441 Infection Control

• The facility must establish and maintain an Infection Control Program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of disease and infection.

Staff behaviors

• Hand sanitation behaviors
• Staff Illness
• Isolation practices
• Housekeeping practices
• Laundry

Preventive strategies-Facility

• Policies
  • Overall infection control
  • Department specific
• QAPI
  • Hand hygiene
  • Isolation precautions
Preventive Strategies-Physician

- Hand hygiene practices
- Antibiotic usage
- Documentation

Preventive Strategies-Nurses

- Hand hygiene practices
- Early recognition & assessment
- Appropriate collection of C&S specimens
- Competency with dressing changes

Preventive Strategies-STNA's

- Hand hygiene
- Soiled linen transportation
- Isolation precautions
Preventive Strategies - Others

- Hand hygiene
- Compliance with Linen handling P/P
- Housekeeping practices

References

- OHCA White Papers
- AHA Guidelines for ECC 2010
- Ohio Revised Code 4723
- Ohio Administrative Code 4723
- INTERACT 3/4
Objectives Continued...

- Analyze recent IJ citations: F229-1126, F31A, and F329
- Identify behaviors that may put a facility at risk for IJ citation
- Discuss preventive strategies to avoid IJ citations

Civil Monetary Penalties (CMP)

- Two ranges:
  - Upper range $3050 to $10,000 penalty per day
  - Lower range $50 to $3000 per day
  - Per instance CMP $1000 to $10,000

How CMP’s are Used:

- The law provides that collected CMP funds may be used to support activities that benefit residents, including:
  - Assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility)
  - Projects that support resident and family councils and other consumer involvement in assuring quality care in facilities; facility improvement initiatives approved by the Secretary (including joint training of facility staff and surveyors, technical assistance for facilities implementing quality assurance programs)
  - The appointment of temporary management firms, and other activities approved by the Secretary
From the Eyes of a Surveyor:

- If a facility violates a regulation because it does not meet a professionally recognized standard of care, be prepared to specify the standard & back it up. Support the deficiency with written material such as:
  - Nursing textbooks
  - Professional articles
  - CMS publications on the potential problem
- Do NOT assume that a facility that violates its own policy automatically violates a related regulation. The facility may successfully argue that its policy exceeds professional standards, & therefore cannot be used to prove a deficiency

Resident Behaviors and Facility Practices: Abuse Tags

- F221—The right to be free from physical restraints
- F222—The rights to be free from chemical restraints
- F223—The right to be free from abuse and seclusion
- F224—The right to be free from mistreatment, neglect and misappropriation of property
- F225—Requires all allegations to be reported and investigated
- F226—Requires the development and implementation of policies
IJ Bulletin 4th Quarter 2014: F 221: Physical Restraints

- Facility H: F221 Right to be Free from Physical Restraints (J) - Restraints
- Facility failed to ensure a resident was free from physical restraint unnecessary to treat medical symptoms.
- Immediate Jeopardy for one resident when physically restrained and given an intramuscular injection of Invega Sustenna, a long acting anti-psychotic medication, which had been repeatedly refused.
- The resident reported facility staff had physically assaulted her.

Comments/Recommendations: F221 Physical Restraints

- You can not hold a resident down against their will!
- If resident uncontrollable, call 911
- Refusing medication: Notify physician immediately

F223 (42 CFR 483.13(b))

- Abuse
  - The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion

• Facility O: F223 Free from Abuse/Involuntary Seclusion (J) - Physical Abuse
  F225 Investigate/Report Allegations/Individuals (J) - Investigate/Report Abuse
  F226 Develop/Implement Abuse/Neglect, Etc Policies (J) - Policy Abuse

Self Reported Incident, Complaint Investigation, Partial Extended Survey

• Failed to ensure a resident was protected from being physically abused by a staff member resulting in immediate jeopardy for one resident who was smacked on the arm and the mouth by a staff member during personal care.
  • The facility failed to ensure staff to resident physical and verbal abuse was immediately reported to the Administrator, failed to ensure the resident was protected from further abuse and failed to ensure allegations of abuse were thoroughly investigated.
  • The facility also failed to ensure a thorough investigation was completed when a resident who required two-person assistance, was found with bruising after one state tested nurse aide provided incontinence care and alleged the resident was combative during the care.

F223 Intent

• Each resident has the right to be free from abuse, corporal punishment, and involuntary seclusion
  • Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the resident, family members or legal guardians, friends, or other individuals

• For example, if a resident-to-resident altercation occurred, did facility:
  • Have any reason to expect such a problem?
  • Could the facility have prevented it?
**Guidance: Key Terms**

- **Abuse** means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. (42 CFR §488.301)

  - Includes:
    - deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being
    - Presumes instances of abuse of all residents:
      - comatose, cause physical harm, or pain or mental anguish.

- "Verbal abuse": use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or families, or within their hearing distance, regardless of their age, ability to comprehend, or disability

  - Examples: threats of harm, saying things to frighten a resident, such as telling a resident that he/she will never be able to see his/her family again

- "Sexual abuse" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault

- "Physical abuse" includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment

- "Mental abuse" includes, but is not limited to, humiliation, harassment, threats of punishment or deprivation

**Examples:**

<table>
<thead>
<tr>
<th>CMS Definition</th>
<th>Explanation</th>
<th>Examples</th>
</tr>
</thead>
</table>
| Willful infliction of injury | Done on purpose | "That’s it. Just stay in here by yourself."
| Unreasonable confinement | Ornam, restrain, not allow | "You have to...", "If you don’t do...", "You won’t get to go..."
| Intimidation | Threaten, threaten, bully, make a person fearful | "You have to...", "If you don’t do...", "You won’t get to go...", "You want to go..."
| Punishment | Discipline, scold, left off | "You have to...", "If you don’t do...", "You won’t get to go..."
| Deprivation of goods or services that are necessary to attain or maintain physical, mental and psychosocial well-being | Remove, take away | "Well, if you don’t take a bath, you don’t get to go on the field trip..."
Investigating Involuntary Seclusion

- Emergency or short term, monitored separation from other residents will not be considered involuntary seclusion.
- This type of separation may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident’s needs.
- Investigation of possible involuntary seclusion may include looking into one of two possible situations:
  - Residents are living in an area of the facility that restricts their freedom of movement throughout the facility.
  - A resident is temporarily separated from other residents.

Reporting

- A nursing home is required, by Federal regulation, to report alleged violations involving mistreatment, neglect or abuse to the State Agency immediately within ___ hours of the alleged violation being reported.
- The nursing home then must investigate this violation and report the results of the investigation to the appropriate authorities within ___ days.

Ohio Department of Health
DQA/BLTCQ
Health Care Provider and Services:

To obtain real-time information, generate and download reports regarding health care providers that are licensed and/or Medicare/Medicaid certified by the Ohio Department of Health.
Survey Scenario; You are the Surveyor...

- You are on a complaint investigation looking into an allegation of verbal abuse. During your investigation, the resident tells you that a nursing assistant yelled & cursed at her & that three other staff members were nearby when the incident occurred. The resident explains that she was so upset by what the staff member said to her that she reported the incident to the Social Worker.
- You interview the Social Worker who tells you that while she was not present when the incident occurred, she did report the allegation made by the resident to the Director of Nursing (DON).
- You interview the DON who confirms that the allegation was reported to her but as of this date (10 days after the alleged incident), the facility has not completed its investigation. The DON tells you she has not interviewed the resident or the staff that were on duty when the alleged incident occurred.

Select the appropriate F Tag for the deficiency in the preceding scenario, or select that there is no deficiency in the scenario:

- F223
- F224
- F225
- F226
- No deficiency exists

* Right! The facility failed to investigate the allegation of abuse that had been reported. The deficiency should be written at F225.

Staff Behaviors... What do you observe in your care centers?
Meet the Entire Interdisciplinary Team:

- Management (Administrator, DON, Supervisors)
- Direct Care Staff (Nurses/STNA’s)
- Physicians/Physician Assistants/Nurse Practitioners
- Dietary
- Housekeeping
- Therapy (PT/PTA, OT/OTA)
- Restorative (Nurses/STNA’s)
- Social Services
- Housekeeping
- Maintenance
- Other
Preventive Strategies

- If your facility admits patients in need of mental health care, ensure that the appropriate mental health professionals are involved.
- If your facility admits patients with behaviors, ensure that these behaviors are care planned and that appropriate interventions are set in place.
- Staff needs to be aware of an increase in frequency or the escalation of previously identified behaviors and address them as appropriate.
- Resident care plans need to be reviewed and revised after every resident to resident incident and staff should evaluate whether alternative placement is appropriate.

Person Centered Care: Abuse Prevention

“Employees must be able to recognize the signs and symptoms of abuse and believe that they can report allegations to management without suffering negative consequences themselves.”

~National Association of State Units on Aging and
National Center on Elder Abuse

How educated are you and your care community staff???
IJ Bulletin 4th Quarter 2014: F329
Unnecessary Drugs: Coumadin

- Failure to monitor therapeutic blood levels for two of seven sampled residents who received Coumadin, an oral anticoagulant (blood thinning) medication.
- Immediate Jeopardy for one resident who received anticoagulant medication without the needed laboratory tests completed to monitor for the therapeutic blood levels and the resident experienced hematuria (blood in the urine).
- Additionally, this resulted in Immediate Jeopardy for another resident when the facility failed to ensure the resident had the necessary monitoring for blood levels to determine if the levels were within a therapeutic range when receiving Coumadin an anticoagulant (blood thinning) medication along with another drug with a potential drug interaction.

(F329) 42 CFR §483.25(l) Unnecessary Drugs

1. General. Each resident’s drug regimen must be free from unnecessary drugs.

Unnecessary drugs

Unnecessary is any drug when used:
- In excessive dose (incl. duplicate therapy)
- For excessive duration; or
- Without adequate monitoring; or
- Without adequate indications for use; or
- In presence of adverse consequences
- Combinations of any of above
F329 Unnecessary Drugs: Monitoring

• What is purpose of monitoring?
  • To incorporate medication-related goals and monitoring parameters into the resident's comprehensive care plan
  • To optimize medication therapy (benefits) while minimizing adverse consequences (risks)
  • To establish parameters for evaluating the ongoing need for the medications

F-329 Unnecessary Drugs: Monitoring

• Lab tests (i.e. serum medication concentrations) are only rough guides
  • Significant adverse effects can occur even when lab results are within therapeutic range
  • Lab results alone warrant evaluation, but do not necessarily warrant dose adjustment (ex. sub-therapeutic Dilantin level however resident is seizure free)

Investigative Protocol

Objective 1: To determine whether the resident receives:
  • Only medications clinically indicated in the dose and duration to meet the resident’s needs
  • Non-pharmacological interventions when clinically indicated
  • Gradual Dose Reduction (GDR) attempts for antipsychotics unless clinically contraindicated and tapering for other medications
Investigative Protocol

Objective 2:
To determine if the facility and the prescriber:
• Monitor medication for effectiveness and emergence of adverse consequences
• Recognize, evaluate, follow up on medication related adverse consequences

Investigative Protocol

Objective 3:
To determine if the pharmacist:
• Performed MRR monthly and identified existing irregularities
• Reported any identified irregularities to attending physician and DON
• To determine whether facility and/or practitioner acted upon report of irregularity

• Only those medications required to treat the assessed condition should be used in the correct dose & timeframe, etc.
• Periodic assessment is required to identify need to reduce use, or change the drug
• Maximize the effectiveness of the medication by monitoring resident responses routinely & documenting
• Notification of practitioner, if any significant clinical changes, & as needed
Warfarin

- Substance that “thins” the blood
- Clinically used to reduce the body’s ability to form blood clots / to prevent blood clots
- Disrupts the coagulation process in the body
- Trade Names: Coumadin, Jantoven
- One of the most dangerous drugs in healthcare

Thromboembolic Risk

- Deep Vein Thrombosis (DVT)
- Pulmonary Embolism
- Myocardial Infarction
- Stroke

Laboratory & Diagnostic Services

- Facility must provide / obtain laboratory & diagnostic services to meet needs of residents, & monitor service quality & timeliness based on regulations
- Facility must provide / obtain lab or diagnostic services, & upon physician order, promptly notifies the attending physician of the findings
- PT/INR measures blood clotting time & monitors Coumadin
Warfarin
• Frequent Monitoring
• Many Interactions:
  • Food
    • Vitamin K Rich Foods
  • Drugs

Warfarin
• Keep Diet CONSISTENT
• Vitamin K Rich Foods
  • Broccoli ½ cup
  • Brussel Sprouts 5 sprouts
  • Green Cabbage 1 ½ cups
  • Collard Greens ½ cup
  • Endive 2 cups
  • Kale ½ cup
  • Lettuce: Leaf, Red, Romaine 1 ½ cups
  • Chicken, Beef Liver
  • Spinach, Raw 1 ½ cups

Warfarin
• Metronidazole
  • Decreases Warfarin by 50% and monitor Q3Days
• Amiodarone
  • Decrease Warfarin by >25%, and monitor
• Cephalosporins, Levothyroxine
  • Increase Monitor INR
• Gingko, Ginseng, Garlic
  • Glucosamine, Cranberry
Problems with Warfarin

• Underused in geriatric population
• Many drug/food interactions
• Monitoring-labor and time intensive
• Risk of falls n bleeds
  • Caution with Drug-Drug Interactions

F329 Severity Level 4
Immediate Jeopardy Example

➢ Resident receiving Warfarin and **INR is greater than 9 with or without bleeding**
➢ There is **no indication of assessment follow-up to address potentially serious consequences associated with INR level**

F 329 Severity level 3 example:

• **F329 Severity Level 3**
  • Failure to suspend the administration of Warfarin in response to an **INR greater than 4, but less than 9**
  • When **spontaneous bruising or frank bleeding occurs, resulting in the need to transfuse or hospitalize the resident**
F 329 Severity level 2 example:

• Resident is on Warfarin.
• The INR levels are between 4 and 9 without any evidence of bleeding or other symptoms related to the anticoagulation

Staff Behaviors

• Management (Administrator, DON, Supervisors)
• Direct Care Staff (Nurses, STNA’s)
• Therapy (PT/PTA, OT/OA)
• Restorative (Nurses/STNA’s)
• Dietary
• Social Workers
• Physician
• Social Services
• Activities
• Housekeeping
• Other

Preventive Strategies

F329: Coumadin
Admission or re-admission: old meds vs. new meds, based on diagnoses – old or new

Multiple prescribers: hospital physicians &/or specialists; attending; on call physician, hospice, nurse practitioners

New med order for emergency-monitor for relevance in acute phase, stabilized phase, maintenance phase, & obtain order change prn

Psychiatric disorders or distressed behaviors

Specific Clinical Considerations

- Admission or re-admission: old meds vs. new meds, based on diagnoses – old or new
- Multiple prescribers: hospital physicians &/or specialists; attending; on call physician, hospice, nurse practitioners
- New med order for emergency-monitor for relevance in acute phase, stabilized phase, maintenance phase, & obtain order change prn
- Psychiatric disorders or distressed behaviors

Nurse’s responsibilities

- Complete comprehensive assessment on admission, & as indicated
- Understand the medication indications & use, esp. the ones specific to the new diagnoses
- Along with routine clinical assessment, also identify monitoring med actions, side effects, allergies, effectiveness, resident response, etc
- Be aware of potential safety hazards, & any other adverse consequences
Nurses’ responsibilities, continued:

Address, assess, act, notify, obtain orders, & document according to SBAR:

- Situation: significant change of condition info & assessment to physician TIMELY
- Background: most current diagnosis, H & P, labs, tests, nurses’ notes
- Assessment: pertinent data, including VS, BS, pulse ox, pain, S&S. Notify pharmacist prn
- Recommendation: intervention & suggestion
- Response: new order & action & monitor

ASSESSMENT AND CAREPLAN

- Center must complete timely, comprehensive, accurate assessment of functional capacity
- Careplan within 7 days of comprehensive assessment
- IDT prepares/revises careplans based on resident needs & notifies resident, legal rep, family, to attend & participate in care conference

Monitoring/Documentation

- Ongoing Coumadin flow sheet with each date, PT/INR values, specific Coumadin order & changes; list of side effects to monitor
- Complete corresponding documentation
- Notification per facility policy asap:
  - Phone physician w/ side effects, clinical assessment & lab findings, all other pertinent information, & document
<table>
<thead>
<tr>
<th>Date/Time</th>
<th>PT/INR</th>
<th>Order Date/Time</th>
<th>PT/INR Drawn Date/Time</th>
<th>PT/INR Results Rec’d Date/Time</th>
<th>Physician Notification Date/Time</th>
<th>New Medication Order Date/Time</th>
<th>New Lab Orders (PT/INR) Date/Time</th>
<th>Responsible Party Notified Date/Time</th>
<th>Order to MAR Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/14/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9:15 AM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/15/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 AM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/15/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INR 3.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/15/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 AM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/15/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NNO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/15/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Same dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/15/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10AM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/15/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10AM, NNO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/15/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Same dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/15/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 PM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/15/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>–</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mary, daugh</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/15/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10:30 AM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Same dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/15/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 PM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/15/09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coumadin 3mg MB 1st KK 2nd</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ANTICOAGULANT THERAPY

R/T

- DVT
- Pulmonary emboli
- Myocardial infarction
- Open heart surgery
- Dialysis
- Stroke

Prevention of blood clots
- Heart valve replacements
- Heart arrhythmias
- Altered tissue perfusion
- Other__________________
- Other__________________

AEB

- Coumadin (Warfarin)
- Heparin
- Lovenox (Enoxaparin)

Monitor and identify possible side effects of anticoagulant therapy

- Monitor PT/INR per order or at least monthly
- Monitor APTT/PTT per order
- Monitor Hgb and Hct
- Monitor platelets
- Report all abnormal lab results

- Monitor for side effects:
  - Bleeding gums
  - Petechiae
  - Ecchymosis (Bruising)
  - Black, tarry stool
  - Hematuria
  - Hypertension
  - Hypotension
  - Change in pulse pressure
  - Decrease in pulse
  - Headache
  - Dizziness
  - Fever
  - Skin rash
  - Urticaria (Hives)

- Report all side effects or condition changes to physician

- Maintain anticoagulant flow sheet
- Limit foods high in Vitamin K (Green leafy vegetables)
- Use soft bristle toothbrush
- Use electric razor
- Report condition changes to resident/family/legal representative
- Monitor for medication interactions

Pharmacist

Valuable resource:
- Appropriate medication goals
- Recommended actions, doses, & interactions
- Main therapeutic benefit
- Side effects
- Monitoring parameters
- Risks & cautions, especially clinically significant adverse reactions
- Some medications not acceptable for use in older adults or institutionalized individuals
IJ Bulletin: 4th Quarter 2014: Pressure Ulcers

- **Facility L: F314 Treatment/Services to Prevent/Heal Pressure Sores**
  
  11/04/2014 Annual Survey, Extended Survey
  
  The following deficiency represents an incident of past noncompliance that was subsequently corrected prior to this survey. The facility failed to monitor and assess a resident with an immobilizer boot on her left leg which resulted in Immediate Jeopardy when one resident developed an avoidable in-house acquired unstageable pressure ulcer.

- **Facility M: F314 Treatment/Services to Prevent/Heal Pressure Sores**
  
  12/04/2014 Annual Survey, Extended Survey
  
  The facility failed to accurately identify residents at risk for developing pressure ulcers, failed to monitor and re-assess residents with pressure ulcers to determine if the pressure ulcers were improving or declining until the ulcers were Stage IV or unstageable (blackened in color with necrotic tissue), and failed to ensure treatments were completed as ordered.

F 314: 42 CFR 483.25 (c)

- Based on the comprehensive assessment of a resident, the facility must ensure that:
  1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual’s clinical condition demonstrates that they were unavoidable;
  2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infections and prevent new sores from developing.
F314 Intent

Part 1: Residents do not develop pressure ulcers unless they are unavoidable.

Part 2: The facility provides care and services to:
• Promote healing of current ulcers
• Promote prevention
• Prevent infection
• Prevent development of additional pressure ulcers

MDS 3.0 Section M: Skin Conditions

Intent: The items in this section document the risk, presence, appearance, and change of pressure ulcers. This section also notes other skin ulcers, wounds, or lesions, and documents some treatment categories related to skin injury or avoiding injury. It is important to recognize and evaluate each resident’s risk factors and to identify and evaluate all areas at risk of constant pressure. A complete assessment of skin is essential to an effective pressure ulcer prevention and skin treatment program. Be certain to include in the assessment process, a holistic approach. It is imperative to determine the etiology of all wounds and lesions, as this will determine and direct the proper treatment and management of the wound.
Deficiency Determination - “Avoidable vs. Unavoidable”

• Was preventive care
  - aggressive?
  - consistent?
  - appropriate?
  - resident specific?

If not, the development of a pressure ulcer may have been “avoidable.”

Unavoidable

Was it:
• Assessed
• Care planned
• Care plan implemented
• Evaluation of outcomes
• Care plan revised

Unavoidable

Not all pressure ulcers are avoidable
• Multi system organ failure or end of life condition.
• Refusing care and treatment.
Thoughts from a Surveyor Perspective....

“The presence of any one, or even several, risk factors or conditions does NOT make a pressure ulcer “Unavoidable”!

Risk Factors

Intrinsic
- Limited Mobility
- Under-nutrition, malnutrition and/or hydration
- Incontinence
- Increased Age
- Co-morbid conditions (Diabetes, Heart Failure, end-stage)
- Cognitive Impairment
- Resident Refusal of Care
- History of Previous Pressure Ulcers

Extrinsic
- Pressure
- Friction
- Sheer
- Moisture

Risk Assessment Frequency Suggestion

- Significant number of pressure ulcers develop within the first 4 weeks of admission.
- Use a standardize risk assessment on admission
- Repeat weekly for the first 4 weeks
- Repeat quarterly
- Repeat whenever there is a change
Pressure Points

Pressure Ulcer

- A localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction

Staff Behaviors

- Management (Administrator, DON, Supervisors)
- Direct Care Staff (Nurses, STNA's)
- Therapy (PT/PTA, OT/OTA)
- Restorative (Nurses/STNA's)
- Dietary
- Social Workers
- Physician
- Social Services
- Activities
- Housekeeping
- Other
What's in Your Facility Arsenal?
• Standards of Practice
• Facility Policies and Procedures (protocols)
• Regulatory Requirements

What Tools are in Your Box?
• NPUAP Pressure Points:
  • Risk Assessment
  • Skin Care
  • Nutrition
  • Mechanical loading and support surfaces
  • Education

http://www.npuap.org/resources/educational-and-clinical-resources/pressure-ulcer-prevention-points

Skin Care
• Head to toe assessment at least daily
• Mild Cleansing agents
• Use lotion/cream after bathing
• Moisturizers for dry skin
• Minimize environmental factors leading to dry skin (low humidity, cold air)
• Avoid massage over bony prominences
Nutrition

- Utilize your team: Dietician/Diet Technician
- Identify and correct factors compromising protein/calorie intake
- Keep residents hydrated
- Consider supplementation for nutritionally compromised residents

Mechanical Loading and Support Surfaces

- Reposition bed-bound residents at least every 2 hours and chair-bound residents at least every hour
- Use pressure-redistributing devices
- Use lifting devices (trapeze, bed linen, Hoyer lifts)
- Use pillows or foam wedges to off-load pressure from bony prominences
- Maintain head of bed at or below 30 degrees
- Utilize your team: Restorative, OT/PT

Education

- Educate interdisciplinary team (Nursing, Therapy, MD, Dietary, STNAs, Activities, Restorative, residents/families, etc.)
- Competencies
- New Staff Orientation
- Policy and Procedures
- Include information on
  - Etiology, risk factors, risk assessment, skin assessment, nutritional support, bowel and bladder management, treatments, repositioning, documentation, etc.
Principles of Wound Management

- Remove necrotic tissue
- Treat infection
- Fill dead space
- Maintain moist wound environment
- Protect the wound from infection, trauma, and cold

Dressing Categories

- Alginate
- Foam
- Gauze
- Hydrogel
- Hydrocolloid
- Transparent Film

Useful Acronyms:

- **SKIN**
  - **S** = Surface Selection
  - **K** = Keep residents turned
  - **I** = Incontinence care
  - **N** = Nutrition
Acronyms...

• **NO ULCERS**
  - N=Nutrition/Fluid Status
  - O=Observe the skin
  - U=Up and Walking, or turn and reposition
  - L=Lift, don’t drag!
  - C=Clean skin and incontinence care
  - E=Elevate Heels
  - R=Risk Assessment
  - S=Support Surface

Document, Document, Document

The 5 C’s:
- Clear
- Concise
- Chronological
- Continuing
- Complete
Preventive Strategies: OHCA

• Facilities can be cited at an IJ level for pressure ulcer development for stage 4 and infected stage 3 ulcers. Therefore, the development of all stage 3 or unstageable ulcers should be cause for review and possibly a corrective action plan.

• It is significant that the original time frame for the IJ was from September 8, 2013 – February 17, 2014 (168 days), and only one of the cited examples had pressure ulcers from 9/8/13 – January 2, 2014.

• The time frame was later reduced by CMS to only 5 days. Consequently, facilities that have more than one resident with pressure ulcers or a resident with multiple ulcers may be at risk for prolonged periods of immediate jeopardy and should evaluate accordingly.

Questions or Comments?!

We’d like to hear it from you! We will answer your questions as best as we can!

Thank You
Skilled Nursing Facility Abuse, Neglect Misappropriation, Injury of Unknown Source (IUS) Investigation Guide White Paper

Background
All residents have the right to be free from abuse, neglect, and misappropriation of property. The Ohio Department of Health and the Centers for Medicare and Medicaid Services have established regulatory guidelines for reporting and investigating allegations or suspicions of abuse, neglect or misappropriation of resident property, and injuries of unknown source. The goal of this white paper is to assist with skilled nursing facility members' understanding of the overall expectations of the reporting and investigating guidelines. All alleged violations must be reported to the administrator, investigations begun, then reported to ODH within 24 hours, and other officials in accordance with state law. With IUS, it is required that immediate analysis occur once an injury is discovered and immediate reporting once the IUS definition is met. Completed investigations must be submitted to ODH electronically within 5 working days of the incident or its discovery. Investigation form HEA1652 can be found at http://www.odh.ohio.gov/pdf/forms/hea1652.pdf. The ODH decision tree on Abuse, Neglect, and/or Misappropriation and current instructions can be found at: http://www.odh.ohio.gov/odhPrograms/ltc/nurhome/annc/nhann1.aspx.

Primary Federal Definitions
Abuse: the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain or mental anguish.
Neglect: failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.
Misappropriation: the deliberate misplacement, exploitation, or wrongful temporary or permanent use of a resident’s belongings or money without the resident’s consent.
Injuries of unknown source: Must meet both of the following conditions to be classified as an IUS:

- The source of the injury was not observed by any person or the source of the injury could not be explained by the resident, and
- The injury is suspicious because of the extent of the injury or the location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma) or the number of injuries observed at one particular point in time or the incidence of injuries over time

Resident-to-Resident Altercations: An incident involving a resident who willfully inflicts injury upon another resident should be reviewed as abuse under the guidance for 42 C.F.R. § 483.13(b) at F223. “Willful” means that the individual intended the action itself that he/she knew or should have known could cause physical harm, pain, or mental anguish. Even though a resident may have a cognitive impairment, he/she could still commit a willful act. However, there are instances when a resident’s willful intent cannot be determined. In those cases, a resident-to-resident altercation should be reviewed in comparison to the requirements at F323 – Accidents and Supervision.

PROCESS/INSTRUCTIONS for SELF REPORTING
All allegations of mistreatment, neglect, abuse, or misappropriation of resident property will be reported as required by state and federal regulations, including an initial report within 24 hours and a final report within five working days to the Ohio Department of Health according to current guidance and direction provided by that agency.

Injuries of unknown source shall be reported as required by state and federal regulations, including an initial reporting that is to be made “immediately,” meaning as soon as possible, but no more that 24 hours after becoming aware of the injury.

If the facility becomes aware of a potentially reportable occurrence more that five days after the actual event, the investigation and reporting is to be made timely related to the time of becoming aware.

- “CMS interpretation of the requirement is that ALL alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source and misappropriation of resident property be reported immediately to the administrator & to the State Survey & Certification agency.” Determining injuries of unknown source must meet the CMS definition, as above
- The Incident must be reported to the state agency (ODH) immediately upon knowledge of the incident and immediate investigation, including answers of “yes” to any of these questions:
  1. Was the injury observed by any person or explained by the resident?
  2. Is there a written or verbal allegation of abuse/neglect?
3. Is there reasonable suspicion that abuse/neglect may have occurred?

- Further, CMS stated in a letter to ODH in November 2009 “CFR (Code of Federal Regulations) 483.13 9 (c) (2) and S&C 05-09 memo “does NOT allow providers 24 hours to investigate and then determine if an incident is reportable.

It is permissible to submit the final with the immediate report, within twenty four hours of the occurrence as long as the immediacy of reporting requirement is met based on the circumstances.

INVESTIGATION

When investigating an allegation or injury of unknown source the following need to be considered:

- Interview the resident. No matter how impaired the resident may be they may be able to tell something important to the investigation.
- Assess the resident.
- Interview other residents that may have been in the area or have some knowledge of the situation.
- Interview family members.
- Interview staff. Check for staff members that were on duty at the time of the allegation. Interview staff members that were scheduled before and after the allegation occurred. You can never interview too many staff members.
- Interview visitors if necessary.
- Don’t stop interviewing with a few staff members when you think you have the answer. Continue interviewing.
- Review findings with the physician if an injury has occurred to validate the story with the extent of the injury.

CONSIDERATIONS

Regulatory Considerations:

F223: The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion
F 224: deficiencies concerning mistreatment, neglect, or misappropriation of property
F226: deficiencies concerning the facility’s development and implementation of policies and procedures
F: 225: The facility must not employ individuals who have been found guilty of abusing, neglecting, or mistreating residents, by a court of law, or have had a finding entered into the state nurse aide registry concerning abuse, neglect, or misappropriation of resident property. The facility must report any knowledge of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff found guilty, respectively, to the nurse aide registry or other licensing authorities.
F157: Notification of changes: accident w/ need to notify physician, significant change, alter treatment, decision to transfer, change in room, roommate, resident rights

Policy/Process Considerations:

The facility must develop and operationalize policies and procedures to educate all employees for screening and training, protection of residents, and for the prevention, identification, investigation, and reporting/response of abuse, neglect, misappropriation and injuries of unknown source. It is recommended to use the exact regulatory language in the development of your policy and procedure.

Seven Components for facility procedures: See interpretive guidelines in F Tag 226

1. Screening
2. Training
3. Prevention
4. Identification
5. Investigation
6. Protection
7. Reporting/response

Educational Considerations: for resident, legal representative, and staff

1. Facility’s Policies and Procedures
2. Timely notification of incident according to requirements and policy
3. Current ODH self reporting methods and timeframes
4. Investigation instruction to facility management according to policy
5. All appropriate documentation according to requirements, policy and standards of practice
6. Tracking and monitoring of occurrences
7. Action plan to QA/QI process as appropriate based on patterns, trends, sentinel events

Legal/Risk Management Considerations:

- Potential for litigation
- Analyze compliance with resident care plan and effectiveness of plan after each/any occurrence

January 2011
Pressure Ulcer

A pressure ulcer is an area of skin that breaks down when one maintains a position for too long without shifting of the weight or removing the force. The constant pressure against the skin reduces the blood supply to that area, and the affected tissue dies.

A pressure ulcer starts as reddened skin, or an area of altered skin color on various skin tones, but gets progressively worse, forming a blister, then an open sore, and finally a crater. The most common places for pressure ulcers are over bony prominences (bones close to the skin) like the elbow, heels, hips, ankles, shoulders, back, and the back of the head.

The Pressure Ulcer White Paper was created to provide assistance to providers in their efforts to promote the comfort and safety of our residents. We recognize frail elderly are at increased risk for the development of pressure ulcers. Additionally, the development of a pressure ulcer or the improper care of a pressure ulcer places the facility at an increased risk for legal and regulatory issues.

Legal Considerations / Risk Management Considerations

In addition to survey citations and sanctions, actions have been brought against SNFs based on pressure sores in the form of private lawsuits based on negligence, prosecutions by states attorney general (AG) for abuse/neglect, and the federal Department of Justice (DOJ) based on a theory of health care fraud.

The regulatory terms “avoidable” and “unavoidable” are not generally utilized in civil litigation. If sued for negligence, the main issue of inquiry would generally be geared around whether the facility met the standard of care with regard to the assessment, prevention, treatment and evaluation of the pressure ulcer.

The development of pressure sores in some cases can lead to a fraud action brought by the Department of Justice (DOJ). The theory behind this form of federal enforcement is that the provider failed to provide (or provided substandard) pressure ulcer prevention or treatment to the resident, and then billed for and was reimbursed by Medicare or Medicaid. This theory has been used to prosecute SNFs in other states, but not yet in Ohio.

The State Attorney General (AG) has the authority to prosecute a provider under Ohio’s neglect statutes for the development of pressure sores. Although involvement from the AG’s offices would likely only occur in the most egregious cases, it remains a possibility for all providers.

Regulatory/Survey Considerations

Risk of higher level citations, including actual harm and immediate jeopardy is noted with pressure ulcer development or inadequate care and treatment of ulcers developing outside of the facility.

- Inadequate Care and treatment of pressure ulcers result in citations often noted in the following areas:
  - F-314 Pressure Sores and interpretive guidelines, F-157 Notification of Changes, F-272 Comprehensive Assessments, F-279 Comprehensive Care Plans, F-280 Comprehensive Care Plan Revision, F-281 Services Provided Meet Professional Standards, F-309 Quality of Care, F-353 Sufficient Staff, F-385 Physician Supervision, and F-501 Medical Director.
  - Pressure sores can also bring attention from Ohio’s Quality Improvement Organization (QIO) (currently KePro). The QIO role is to assist facilities with problems related to pressure ulcers, under contract with CMS. They would also have the ultimate authority to refer the facility to the Office of Inspector General (OIG) for further attention and possible sanctions.

Policy/Process Considerations

- Policies should include identifying patients at risk for pressure ulcers.
- Each facility should have a well developed system for documenting the existence of a pressure ulcer upon admission, readmission, discharge or following any extended leave of absence.
• Documentation policies should address the recording of the treatments applied, and the improvement or worsening of the ulcer.
• Additionally, systems for monitoring patients with or at risk for pressure ulcers should be in place.
• Each facility should apply adequate pressure ulcer prevention methods as well as educational programs for staff, residents, and family members.
• Policies should be developed that address all disciplines involved in the prevention and treatment of Pressure Ulcers.
• Nutritional Service policies need to be developed that address the nutritional needs of wounds and wound healing.
• Therapy procedures for various treatment modalities should be well defined and cross multiple disciplines who will work together in the care and treatment of ulcers.
• Each facility should utilize Pressure Ulcer Prevention Assessment tools and display a compliant process with treatment interventions, prevention strategies, nutritional interventions and the review of unavoidable ulcers due to co morbid conditions.
• Care planning should be in place that is shows the proactive interventions for each risk identified as well as their effectiveness.

Purchase Considerations:
• The selection of appropriate support surfaces should address the prevention abilities of the product to off load the at risk tissue, regardless of where the at risk tissue is located on the body.
• Providers should follow all manufacturers’ guidelines on the use of any product.

Educational Considerations:
• Staff education, annually and upon hire, should include the identification of a pressure ulcers on all skin tones, the adequate staging of pressure ulcers, the appropriate treatment based on the various forms of ulcers as well as the standards behind prevention.
• Additional staff education should include use of risk assessment tools, selection of support surfaces and the demonstration of positioning to prevent ulcer development.
• GPRA (Government Performance Results Act of 1993) was to improve public confidence in the federal government by holding federal agencies accountable for the achievement of program results that are publicized. CMS’s 2006 goals, adopted 4/1/06 are to reduce restraints+ pressure sores in NFs – utilizing Quality Measures/MDS data

<table>
<thead>
<tr>
<th>Pressure Ulcers</th>
<th>Baseline QM</th>
<th>Goal QM</th>
<th>Stretch Goal QM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region V</td>
<td>7.8</td>
<td>7.4</td>
<td>6.8</td>
</tr>
<tr>
<td>Nation</td>
<td>8.5</td>
<td>8.0</td>
<td>7.5</td>
</tr>
<tr>
<td>Ohio</td>
<td>8.5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recent Ohio data:
3rd quarter 2006 = 13 for hi risk, 2 for low risk
3rd quarter 2007 = 12 for hi risk, 2 for low risk

Additional Information:

http://www.npuap.org
http://www.mao.org/bestpractices/PDF/BPG_Pressure_Ulcers_v2.pdf
http://www.epuap.org/glprevention.html
http://www.kennedyterminalulcer.com
http://www.medicaledu.com/pressure.htm
http://www.medicaledu.com/staginh.htm
http://www.npuap.org/PDF/preventionpoints.pdf
http://www.nhcqf.org/QI_Services/NursingHomes/Topics/Pressure%20Ulcer%20Toolkit%202006/1-Guideline
http://www.health.state.mn.us/div/fpc/cww/pressureulcersbrochure.pdf
http://www.RD411.com
http://www.Wounds411.com


April, 2008
Coumadin, also known as crystalline warfarin sodium, is an anticoagulant (blood thinner) that is prescribed for residents who are at risk of forming blood clots. It is used to lower the chance of blood clots forming in the body. Blood clots can block the flow of blood to vital organs and can cause serious health problems such as stroke, heart attacks, or other conditions such as blood clots in the legs or lung.

Vitamin K is essential for the formation of blood clots. Residents receiving Coumadin must be monitored closely because Coumadin inhibits the natural blood clotting process by decreasing the activity of vitamin K thus increases the chance of bleeding.

Coumadin is essentially completely absorbed after oral administration with peak concentration generally attained within the first 4 hours. The terminal half-life of warfarin after a single dose is approximately one week; however the effective half-life ranges from 20-60 hours. The effects of Coumadin may become more pronounced as effects of daily maintenance doses overlap. Routine lab work must be performed to calculate the correct dose of Coumadin to avoid serious complications.

According to statistics, adults 60 years and older appear to demonstrate an increased sensitivity to Coumadin, and are classified at a higher risk than younger residents. The cause of the increased sensitivity is unknown. This White Paper on Coumadin was developed because the administration of Coumadin places such a high risk on our frail elderly residents.

Legal/Survey Considerations
- Coumadin issues often rise to the level of immediate jeopardy survey citations and possible litigation;
- Heparin and Plavix are low risk anticoagulants and don’t require routine follow up lab work (consult with physicians and pharmacist); a PTT may be done after administering heparin when all the lab work is stabilized;

Regulatory Considerations
- F 281, Resident Assessment
  The services provided or arranged by the facility must meet professional standards of care;
- F 309, Quality of Care
  Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well being, in accordance with the comprehensive assessment and care plan;
- F 329, Unnecessary Drugs
  Each resident’s drug regimen must be free from unnecessary drugs, which includes, without adequate monitoring.
- F332, Medication Errors
  The facility must ensure that it is free of medication error rates of 5 percent or greater
- F333, Medication Errors
  Residents are free of any significant medication errors.
- F428, Drug Regimen Review
  The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist, and the pharmacist must report any irregularities to the attending physician, and the director of nursing, and these reports must be acted upon.
• **F 502, Laboratory Services**
  The facility must provide or obtain laboratory services to meet the needs of the resident. The facility is responsible for the quality and timeliness of the services;

• **F 508, Radiology and other Diagnostic Services:**
  The facility must provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

**Policy Considerations**
- Develop facility policies and procedures to include the following:
  - A Quality Assurance program to monitor the administration of Coumadin and follow up lab work;
  - Monitor for trends and relate those trends to physicians and the medical director;
  - Include all past lab results as well as current lab results when reporting to physicians;
  - Various tools recommended for recording and monitoring coumadin and related lab work are provided on the OHCA website, the link for which is listed at the end of this document;
  - Policies should not suggest standard time frames for follow-up lab work; but recommend that each resident has specific individualized orders for follow up lab work, as that is essential for proper control;
  - Obtain acknowledgment of receipt for all lab work that is faxed to physicians, don’t assume it was received;
- Care plan for increased risk of bleeding for residents receiving Coumadin, as well as aspirin and/or Plavix, with or without Coumadin.

**Educational Considerations**
- Educate all facility staff who provide direct resident care;
- Educate staff, residents and families about the effects of Coumadin and include the following:
  - Monitor for, and report at once to the physician any signs or symptoms of bleeding and/or unusual bruising;
  - Teach direct care staff/STNAs about signs or symptoms of bleeding and/or unusual bruising;
  - Monitor for medications that interact with Coumadin;
  - Be aware of certain foods that may affect Coumadin;
  - A number of OTC medications and Herbals may interact with Coumadin and if being administered, should be discussed with physician;
- Administrative staff must continually monitor the Quality Assurance program to be sure that the program is followed;
- Monitor for increased bleeding or bruising anytime Coumadin is started or stopped;

**Purchasing Considerations**
- ProTime and INRatio portable units are approved for professional and home use allowing healthcare providers immediate INR test values resulting in improved care. The CoaguChek S is available for professional use only. Real-time results allow immediate counseling, education and treatment without the delay of traditional lab testing.
- Consider the approximate cost of portable units: INR = $2700; Protome = $1700; and CoaguCheks = $1300;
- Portable units are sensitive to heat and cold;
- Portable unit strips are very expensive and can range from $7.00 and more per strip;
- Consider portable units upon discharge for home use;
- To access information about portable units go to http://www.ptinr.com/data/templates/article.aspx?z=5&articleid=234&u(patient&ur=true

**OHCA website link to Coumadin White paper and related materials:** [http://www.ohca.org/content/view/409/](http://www.ohca.org/content/view/409/)

*December 8, 2006, updated August 2007*
White Paper
Unnecessary Medications

Introduction and Background
Medications are an integral part of the care provided to residents of nursing facilities. They are administered to try to achieve various outcomes, such as curing an illness, diagnosing a disease or condition, arresting or slowing a disease process, reducing or eliminating symptoms, or preventing a disease or symptom. Any medication or combination of medications—or the use of a medication without adequate indications, in excessive dose, for an excessive duration, or without adequate monitoring—may increase the risk of a broad range of adverse consequences such as medication interactions, depression, confusion, immobility, falls, and related hip fractures. While assuring that only those medications required to treat the resident's assessed condition are being used, reducing the need for and maximizing the effectiveness of medications are important considerations for all residents. F329 – Unnecessary Medications has steadily become a top citation for facilities during the survey process.

Legal/Risk Management Considerations
Potential negative outcomes of unnecessary drugs may include but are not limited to those that are directly a result of the medication effect, i.e. side effects, allergies, inadequate monitoring, or a more indirect result of decline in function. These might include: decline in the resident’s physical condition (ability to ambulate), contractures, increased incidence of pressure ulcers, delirium, agitation, and incontinence. In addition the use of unnecessary medications may increase the potential for falls and accidents.

Regulatory/Survey Considerations
F329 states that each resident’s drug regiment must be free from unnecessary drugs. An unnecessary drug is any drug when used: in excessive dose (including duplicate drug therapy); or for excessive duration; or without adequate monitoring; or without adequate implications for use; or in the presence of adverse consequences that indicate the dose should be reduced or discontinued.
The intent of this requirement is that each resident’s entire drug/medication regimen be managed and monitored to achieve the following goals:

- The medication regimen helps promote or maintain the resident’s highest practicable mental, physical, and psychosocial well-being, as identified by the resident and/or his/her representative(s) in collaboration with the attending physician and the facility interdisciplinary team.
- Each resident receives only those medications, in doses and for the duration clinically indicated to treat the resident's assessed condition(s);
- Non-pharmacological interventions (such as behavioral interventions) are considered and used when indicated, instead of, or in addition to, medication;
- Clinically significant adverse consequences are minimized; and
- The potential contribution of the medication regimen to an unanticipated decline or newly emerging or worsening symptom is recognized and evaluated, and the regimen is modified when appropriate.

Additional potential survey citations, if Unnecessary Medications tag is being investigated at your facility include but are not limited to:
- F154, F155, Notice of Rights & Services, Free Choice
- F272, Comprehensive Assessments
- F281, Resident Assessment
- F310, Decline in ADL
- F319, F320, Mental & Psychosocial Functioning
- F327, Hydration
- F157, Notification of Changes
- F279, F280, Comprehensive Care Plans
- F309, Quality of Care
- F315, Urinary Incontinence
- F325, Nutritional Parameters
- F385, Physician Supervision
Policy/Process Considerations

Facilities should assure that the following systems are in place:

- Evaluation and assessment of the selection of medication(s) based on assessing relative benefits and risks to the individual resident.
- Evaluation of the resident’s signs and symptoms, in order to identify the underlying cause(s) including adverse consequences of medication(s).
- Identification of which classes of medications need special monitoring such as lab work, vital signs, behavior tracking, etc.
- Identification and monitoring of those meds where gradual dose reductions (GDR) need to be attempted or documentation is present to show GDR is contraindicated.
- Identification and monitoring of residents for EPS (extrapyramidal symptoms) or tardive dyskinesia. Monitoring of the care plan to assure one is initiated and updated to reflect medication management goals.
- Monitoring of the care plans/nursing notes to assure that non-pharmacological interventions are included in documentation to minimize the need for medications, permit the use of the lowest possible dose or allow medications to be discontinued.
- Addressing the Medication Regimen Review (MRR) recommendations where there is no response from the physician.

Educational Considerations

- Staff education appropriate to the monitoring considerations for various classes or types of medications, including associated documentation.
- All Staff education regarding non-pharmacological approaches prior to medicating for a symptom, including a system for communication to direct care staff (i.e., sign/symptoms of bleeding for resident on coumadin).
- Proper assessment of each resident’s drug regimen by all disciplines to assure each medication is necessary, including Consultant Pharmacist and Physician.
- Proper care planning of medication management; upon admission and timing of necessary updates.
- Annual inservice on Unnecessary Medications and medication pass audits.
- Staff education on communicating with pharmacy provider any questionable medication order.
- Educational programming addressing documentation of all aspects of the systems and processes for managing and monitoring medication regimes.

Resources

- RAP for Psychotropic Drugs
- State Operations Manual Appendix PP, Interpretive Guidelines
- Suggested Laboratory Monitoring Parameters for Commonly Used Medications
- Suggested Non-Pharmacological Considerations for Common Conditions in LTC
- AIMS, DISCUS
- Current drug reference manuals
- OHCA White Paper: Use and Risks of Coumadin Therapy
- Consultant Pharmacist

January 2009