Overview of Presentation

- Describe the requirements of the regulations and best practices related to drugs and biologicals
  - Introduction
  - Meeting the standard for drugs and biologicals
  - Qualified individuals
  - Ordering
  - Administration
  - Disposing
- Issues related to CII medications
  - Federal and State laws
  - Partial fills
  - Emergency orders
  - Signature requirements

Overview of Presentation

- Infection Control
- Medication Profile Review
  - Frequency
  - Documentation
  - Out-source
  - In-House
- Patient’s Rights
- Drugs that are generally not cost effective
- 1st generation vs. 2nd generation antipsychotics
- PDS Syndrome
- Medication related QAPI
- Conclusions
Introduction to Conditions of Participation

- The Hospice Final Rule was published in the Federal Register on June 5, 2008 and became effective December 2, 2008
  - Hospices had an additional 60 days for QAPI requirements which went into effect on February 2, 2009
- The new COPs are patient-oriented, founded on evidence and standards of practice, and emphasize quality improvement and patient outcomes.
  - Medication therapy management (MTM) is emphasized throughout the new VOPs

Hospice Regulations

Survey Focus- Outcomes!

- The outcome-oriented survey process emphasizes the hospice’s performance and its effect on patients
  - Surveyors instructed to focus on patient health and safety and to look at outcomes or potential for poor outcomes
  - All conditions viewed relative to outcomes for the patient/family
  - Goals should reflect patient/family preferences
- Survey Intent
  - Evaluate each CoP in the most efficient manner possible
  - Surveyor considers interrelatedness of the regulations while evaluating compliance through observations, interviews, home visits, and record reviews
Data Elements – Patient Outcomes

Outcome achieved.
Continuously assessed.

Patient would like a pain score of 4 or less out of 10 as an outcome goal.

Interventions implemented:
Patient individualized plan of care outcome goal.

Patient pain will be 4 or less on a scale of 1-10.
Continuously assessed.

Preparedness:
Hospice providers should develop a strategy to remain compliant with the regulations all of the time.

Survey readiness “flurry” is not productive:
- Time consuming
- Stressful
- Not efficient
- Expensive

Compliance is not an EVENT, it is a PROCESS.

Knowledge:

- All staff should have a basic knowledge about hospice regulations.
- Depending on their job responsibilities, more in depth knowledge about the regulations may be required.

Preparedness:
Hospice providers should develop a strategy to remain compliant with the regulations all of the time.

Survey readiness “flurry” is not productive:
- Time consuming
- Stressful
- Not efficient
- Expensive

Compliance is not an EVENT, it is a PROCESS.
Meeting Standard: 418.106 Drugs and Biologicals

- The hospice must employ or contract with and individual to assure that medications meet each patient’s needs
  - PBM or other company/individual that provides such services
  - Internal resources that meet the standard
  - Requirements of individuals
- Pharmacist are not required to be a member of IDG or attend IDG meetings

Meeting Standard: 418.106 Drugs and Biologicals

- Who is qualified to assure that medications meet the needs of the patient? 418.106 (1)(a) L 688
  - Hospices must confer with an individual with education and training in drug management
    - Licensed pharmacists
    - Physicians who are board certified in palliative medicine
    - RNs who certified in palliative care
    - RNs and NPs who complete a specific hospice or palliative care drug management course
  - The hospice must be able to demonstrate that the person has specific education and training in drug management

Meeting Standard: 418.106 Drugs and Biologicals

- 418.106 (2) L 689
  - A hospice that provides inpatient care directly in its own facility must provide pharmacy services under the direction of a qualified pharmacist who is an employee of or under contract with the hospice. The provided pharmacist services must include evaluation of a patient’s response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.
418.106 (b) Standard: Ordering of Drugs
- Ordered only by a physician or NP
- If ordered verbally or via electronic transmission:
  - Must be given to nurse, NP, MD or pharmacist
- What about orders left on a recording?
  - OK, but must be reviewed by a pharmacist prior to processing
  - Be sure to leave all pertinent information

Schedule II Medications
- Signature requirements
  - Pharmacy must have a signed order PRIOR to dispensing unless “Emergency” order
  - Faxed, signed order may serve as the original- no follow up prescription needed
- Partial fills
  - MDs may order 60 day supply- pharmacy can fill 15 day supply x 4.

Schedule II Medications
- Emergency Prescriptions
  - Allowed in Alabama- not in all states
- Requirements/Restrictions
  - Verbal order may be accepted by pharmacist
  - Order may only be for emergency supply- in Alabama, defined as 72 hour supply
  - Prescriber must make the call, not his/her agent
  - MD must send follow up signed order to the pharmacy within 7 days for emergency supply only
  - Pharmacy required to report to DEA if Rx not received
418.106 (c) Standard: Dispensing of Drugs

- The hospice must:
  - (1) Obtain drugs from community or institutional pharmacy
  - (2) If hospice has IPU, they must:
    - Have written policy that promotes dispensing accuracy
    - Maintain records of receipt and disposition of all controlled drugs

418.106 (d) Standard: Administration of Drugs

- (1) The IDG must determine the ability of patient and/or caregiver to self-administer drugs in the home setting
- (2) In an IPU, meds can be given only by:
  - Nurse, MD, other- according to State law
  - An employee who has completed State-approved program on medication adm.
  - The patient- upon the approval by the IDG

418.106 (e) Standard: Labeling, Disposing, Storing of Drugs

- (1) Labeling- in accordance with current practice
- (2) Disposing of controlled drugs (i) In home setting- Hospice must have written P&P
  - (A) provide a copy of P&P to patient/family
  - (B) Discuss P&P with patient/family
  - (C) Document providing and discussing P&P
418.106 (e) Standard: Labeling, Disposing, Storing of Drugs

- Disposing of controlled drugs (ii) In IPU, hospice must dispose of drugs in compliance with hospice policy and State and Federal requirements and maintain records of receipt and disposition of drugs.
- Undocumented PRN doses are often responsible for discrepancies.

418.106 (e) Standard: Labeling, Disposing, Storing of Drugs

- (3) Storing- In an IPU- no specific storage requirements in home setting
  - (i) Drugs must be stored in secure area in locked compartments. Only personnel authorized to administer drugs may have access to locked compartments
  - (ii) Discrepancies must be immediately investigated by the pharmacist and administrator and where required, reported to the appropriate State authority.
  - A written account must be made available to State and Federal officials if required by law or regulation.

Comfort Care Kits in LTC Facilities

- Problems
  - Storing
  - Receipt and disposition records
  - Accountability
- Possible solution
  - Work with facility to include needed hospice medications in the facility stat cabinet/emergency kit
418.110 (i) Infection Control

Infection Control

- Hospice must maintain a coordinated agency-wide program for surveillance, identification, prevention, control, and investigation of infectious and communicable diseases
  - Must be an integral part of the hospice’s QAPI program
    - Monitor work related employee illness and infections
    - Analyze them in relation to patient infections
  - Take appropriate actions when an infection or communicable disease is present to prevent its spread among staff, patients, family and visitors

Infection Control

- The hospice must provide infection control education to employees, contracted providers, patients, and family members and other caregivers
  - Probes 418.60 (c)
    - Is hospice staff aware of infection control principles and procedures?
    - Do they demonstrate this knowledge during home visits?
    - During home visits ask the patient/family or other caregivers to describe infection control education they have received
Survey Readiness Tips

- Ensure that you have an adequate "infection control nursing bag" policy/procedure for hospice staff that visits patients in their home
- Ensure that patient/family received education materials and training about infection prevention and control in the inpatient and home setting
- Consider adopting an annual infection control education update for your direct patient care staff
- Promote infection prevention and control within the hospice organization
- Display infection prevention and control posters
- Support health promotion activities for hospice staff
- Encourage hospice staff to obtain flu shots during flu season

Basic Antibiotics

- Fluroquinolones
  - Cipro- available in generic
- Macrolides
  - Erytab 333- Generic- Enteric coated base- time released
- Sulfas
  - Bactrim DS- available in generic
- Cephalosporins
  - Cefdin- Cefuroxime- Generic
- Tetracyclines
  - Doxycycline - Generic
- Flagyl
  - Metronidazole- Generic

Possible Unnecessary Expense for Antibiotics

- Xifaxan
- Levaquin except for CAP from MDR S. Pneumoniae
- Zyvox
418.52 Patient’s Rights

- Patients have a right to:
  - Receive effective pain management and symptom control
  - Be involved in developing the plan of care
  - Refuse care or treatment
  - Choose his or her attending physician
  - Have a confidential clinical record
  - Be free from abuse or neglect
  - Receive information about services covered under the hospice benefit
  - Receive information about the scope and limitations of services that hospice will provide

Patient’s Rights 418.51 (c)(1)

- Effective Pain Management
  - Assessment
    - Escalating existing pain
    - Emergence of new pain
    - Measurement / evaluation
  - Treatment
    - WHO pain ladder
    - Consider patient goals
    - Medications
      - Use all agents available as appropriate
      - Methadone
      - Adjunct

- Existential Suffering
  - Palliative Sedation

Remember…

If we know that pain and suffering can be alleviated, and we do nothing about it, then we ourselves become the tormentors.

- Primo Levi
Meeting Standard 418.54 (c) Comprehensive Assessment

- Hospices need to be prepared to:
  - Describe process for medication review, including how adverse effects and drug interactions are identified.
  - Describe process followed in patient/family is non-compliant.
  - Describe how patients/families are educated about pain management.
  - Describe how symptoms are assessed and re-assessed.
  - Describe how a patient is monitored when a new medication is added or the dose is altered or medication is discontinued.
  - Demonstrate that common side effects of medications were anticipated and preventive measures were implemented.
  - Show that the medications the patient is currently taking are the same as the ones listed on the POC.

418.54 (c)(6) Initial and Comprehensive Assessment – Medication Profile Review

- A review of ALL prescription and OTC, herbal and alternate treatments. Includes but not limited to identification of the following:
  - Effectiveness of drug therapy.
  - Drug side effects.
  - Actual or potential drug interactions.
  - Duplicate therapy.
  - Drug therapy associated with laboratory monitoring.

418.54 (c)(6) Initial and Comprehensive Assessment – Medication Profile Review

- Drug profile must be completed within 5 days of admission as part of the comprehensive and updated at least every 15 days or with a change in the patient’s status.
- Nurses should document a full medication profile, including OTC and herbal medications.
- Not required to document relationship of drug therapy to terminal illness or related condition but encouraged to do so.
418.54 (c)(6) Initial and Comprehensive Assessment – Medication Profile Review

Best Practices for Performing a Medication Profile Review
- When obtaining a medication history, the nurse should:
  - Involve caregivers
  - Ask to look at all prescription bottles
  - Verify that medications are labeled correctly
  - Capture full dosing information for each medication:
    - Name
    - Strength
    - Form: tab, cap, XL, CR
    - Dose
    - Route
    - Frequency
    - Last dose taken
    - Reason for medication

- Use probing questions to trigger the patient’s memory on what they are currently taking:
  - What do you take all the time?
  - What do you take only when you need it?
  - What is this medication for?
  - When do you take this medication?
  - Do you ever NOT take your medication and why?

- Ask about OTC and herbal meds and nutritional supplements
- Ask about meds not taken orally: inhalers, patches, creams, drops
- Assess the health literacy and compliance potential of the patient/caregiver
Best Practices for Performing a Medication Profile Review

- Take steps to simplify the patient’s drug regimen
  - Remove/discard old or expired drugs
  - Consider non-pharmacological therapies
  - Use sustained release products if appropriate and cost effective
  - Use the fewest meds in the simplest form to achieve the therapeutic goal
  - D/C meds that are not effective or don’t meet goals of hospice care
    - Alzheimer’s meds?
    - Palliative Chemotherapy?
    - Pulmonary medications?
    - Establish relationship of medication to terminal diagnosis
    - Statins
    - Anti-platelet agents
    - Others

- On admission and with medication changes, a review of the patient’s medications, allergies and medical conditions should be conducted to:
  - Assure accuracy and completeness of the order
  - Assess appropriateness of dose, route of administration, dosage schedule and dosage form
  - Identify previous allergic or adverse reactions to a previous medication or one that is chemically similar
  - Identify drug-drug or drug-disease interactions or contraindications
  - Recommend appropriate changes

- Verify that the medication is safe and effective and is the most cost effective solution for the patient’s symptom
- Assess symptoms to determine if it may be the result of an adverse effect of another medication
- Ensure that the patient is not receiving inappropriate duplicate therapy
  - Medications in the same class
  - Multiple medications for the same reason
- Use one medication to treat multiple symptoms when possible
- Suggest alternate routes of administration when appropriate
  - Inhaled medications
  - Topical medications
  - Rectal medications
Medications that are generally NOT the most cost effective

- Xopenex (Levalbuterol)
- Nexium (Esomeprazole)
- Lexapro (Escitalopram)
- Seroquel XR
- Paxil XR
- Coreg CR
- Glucophage XR, Glumetza
- Zyloprim CR
- Lubix CR
- Requip XL
- Arimtrax (Lubiprostone)
- Effexor XR
- Avinza
- Kadian
- Brovana (Arformoterol)
- Symbricort
- (Budesonide/Formoterol)
- Exelon patch (Rivastigmine)
- Azilect (Rasagiline)
- Clarinex (Desloratadine)
- Prialt (Dextromethorphan)
- Ambien CR
- Imegia (Paliperidone)
- Detrol LA
- Ditropan XL
- Oxystro (Ditropan patch)
- Atypical or Second Generation antipsychotics

Coming Soon

- Atenolol LA
- Doxazosin SA
- Amlopidine SA
- Furosemide SA
- HCTZ LA
- Plavix CR
- Enalapril XL
- Enalapril LA
- Maxzide SA
- Lovastatin LA

Atypical or Second Generation Antipsychotics (SGAs) vs. Conventional Agents

<table>
<thead>
<tr>
<th>SGAs</th>
<th>Conventional Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zyprexa</td>
<td>Haloperidol</td>
</tr>
<tr>
<td>Risperdal</td>
<td>Chlorpromazine</td>
</tr>
<tr>
<td>Seroquel</td>
<td>Fluphenazine (Prolixin)</td>
</tr>
<tr>
<td>Geodon</td>
<td>Loxapine (Loxitane)</td>
</tr>
<tr>
<td>Invega</td>
<td>Perphenazine (Trilafon)</td>
</tr>
<tr>
<td>Abilify</td>
<td>Thioridazine (Mellarii)</td>
</tr>
<tr>
<td>Clozapine</td>
<td>Thiothixene (Navane)</td>
</tr>
<tr>
<td></td>
<td>Trifluoperazine (Stelazine)</td>
</tr>
</tbody>
</table>
CATIE Study Data

- What is CATIE? Clinical Antipsychotic Trials of Intervention Effectiveness
  - Phase I- Determine which meds provide best Tx
  - Phase II- Help choose alternate med when 1st choice was not satisfactory
  - Phase III- Analyzes economic impact
- Why is CATIE Important?
  - Schizophrenia Study
  - AD Study
  - Compares Atypical and Conventional agents
    - Older agents generally performed as well as newer agents
    - EPS was not seen more frequently with older agents
    - On the whole, newer agents have no substantial advantage
  - Head to head drug comparisons
- Most important message
  - Antipsychotic treatment must be individualized
  - Newer agents cannot always be replaced with older agents

PDS Syndrome

- Example
  - Aggrenox- Dipyridamole + Aspirin
  - FDA classified Dipyridamole as a desi drug
    - Not proven effective
    - Only official indication is IV to conduct a stress test
  - Bi introduced Aggrenox on the strength of clinical trials that showed Aggrenox was better than placebo
  - Annualized sales of approximately $331 million for the twelve months ended May 2008

PDS Syndrome

- Hydrocodone/APAP
  - 2.5/500
  - 5/325
  - 5/500
  - 7.5/325
  - 7.5/650
  - 7.5/750
  - 10/325
  - 10/500
  - 10/650
  - 10/660 - recent
  - 10/750
- Co-Gesic (5/500)
- Lorcen (10/650)
- Lorcen Plus (7.5/650)
- Lortab (several)
- Maxidone (10/750)
- Norco (several)
- Vicodin (5/500)
- Vicodin ES (7.5/750)
- Vicodin HP (10/660)
- Xodol (10/300, 5/500, 7/300)
- Zydone (5/400, 7.5/400, 10/400
PDS Syndrome

- PDS
  - Pizza
  - Doughnuts
  - Sandwiches

Examples of Medication-Related QAPI Projects

- Queries by drug or drug class
  - Anticoagulants- Monitor INR
  - Meperidine or Propoxyphene- reduce the use of inappropriate medications
  - Antipsychotics- examine use in dementia and if non-pharm measures are employed
  - Antibiotics- Infection control measures
- Patients receiving routine opioids not on a bowel regimen
- Patients receiving long acting pain meds with no PRN breakthrough meds ordered
- PRN meds ordered at the appropriate interval
- Patients receiving long acting inhaled beta agonists with no rescue meds ordered

Case Study

- AW is a 54 yo female with end stage pulmonary hypertension
- Pain score 9/10 most of the time, 5-6 at best
- Complaining of "lung pain"
- Current medications
  - Oxycontin 120mg TID
  - Percocet 4-6 tabs per day
  - Lortab 10 3-4 tabs per day
  - MS IR 30mg 6 per day
  - Roxanol 20mg/ml 6-8 doses/day
  - MS ER 100mg TID
  - MS SQ 3mg/hr
  - MS SQ bolus doses 6mg q hr
  - Methadone 10mg BID
Case Study

- WC is a 73 yo male with lung cancer with bone mets
- Uncontrolled general pain and leg pain
- Pain score in 9/10
- Current pain meds are Fentanyl 100mcg 4 patches every 48 hours, MSIR 60mg q 1 h prn BTP

Case Study - Recommendations and Follow Up

- Recommend 30mg methadone q12h with 60mg morphine q 1hour prn BTP.
- NSAID for bone mets
- Monitor for excessive sedation
- Liberal use of BTP medication encouraged
- Follow up in 24 hours x 3
  - Pain improved to 4-5/10
- Subsequent follow up in 4 days- pain improved to 1-2/10
- Subsequent follow up in 1 & 4 weeks- one additional increase of methadone to 50mg q12h.

Conclusions

- The new COPs have a strong emphasis on appropriate medication therapy management and monitoring
- Important new standards include:
  - Hiring or contracting with an individual with special training in drug management
  - Documentation of all medications on the drug profile
  - Medication profile review
  - Disposal of controlled medications
  - QAPI
THANK YOU!!

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?? QUESTIONS ??