Surveying to Antipsychotic Use in SNFs

July 19, 2012

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Goals and Objectives

- Be familiar with the CDPH-DHCS Antipsychotic Collaborative Executive Report
- Understand the national focus on antipsychotic medications and CDPH alignment with CMS initiatives
- Determine survey sample selection for residents receiving antipsychotic medications
- Understand and be able to implement the new CDPH "Antipsychotic Use Survey Tool" and supplemental guidance
- Discuss elements of SNF informed consent for antipsychotic medications
- Identify regulatory non-compliances related to SNF antipsychotic use and informed consent

Antipsychotic Use in SNFs

- Prescribing of antipsychotic drugs in nursing home residents:
  - More than one of every four Medicare beneficiaries in nursing homes (27.6%) received antipsychotics—the highest reported rate in nearly a decade.
  - Approximately 693,000, or 27.6%, of all Medicare beneficiaries in nursing homes received at least one antipsychotic during the study period. Of these:
    - Approximately 13% received duplicative drug therapy;
    - Over half (58.2%) of treated residents received antipsychotic therapy not in accordance with nursing home guidelines;
    - One in four patients (23.4%) had no appropriate indication for use;
    - Nearly one in five (17.2%) had daily doses exceeding recommended levels, and
    - 17.6% had both inappropriate indications for use and high dosing.

Briesacher BA, et al. The Quality of Antipsychotic Drug Prescribing in Nursing Homes. *Archives of Internal Medicine.* 2005; 163: 1280.

Antipsychotic Use in SNFs

CMS OSCAR data reflects NH antipsychotic use remains unchanged over 3 years: 24.2% (approximately one in four residents) receive these medications in CA

CMS Online Survey, Certification and Reporting (OSCAR) data 2010, 2011 and 2012; QIES link: https://web.qiesnet.org/qiestosuccess

CDPH/DHCS Antipsychotic Collaborative Executive Report

- Encompasses outcome of 42 NH antipsychotic collaborative investigations May 2010 – September 2011
  - Methodology:
    - DHCS Pharmacy Benefits Division shared Medi-Cal beneficiary antipsychotic utilization data with CDPH
    - CDPH conducted investigations through the complaint process utilizing a team of Pharmaceutical Consultants
- Identifies quality of care issues associated with NH antipsychotic use
- Posted to CDPH internet website 5/31/12: http://www.cdph.ca.gov/programs/LnC/Documents/AntipsychoticCollaborativeExecutiveReportFinalMay2012.pdf

CDPH/DHCS Antipsychotic Collaborative Executive Report

- Investigative findings revealed:
  - 29/42 (69%) of investigations resulted in regulatory deficiencies related to inappropriate antipsychotic use
  - Of those 29 investigations, 85% of the time the consultant pharmacist failed to identify the inappropriate antipsychotic use
  - In 18/29 investigations (62%), facilities received consultant pharmacist services below cost
  - In 16/29 investigations (55%), inadequate development of antipsychotic nursing care plans
  - In 14/29 investigations, inadequate adherence to informed consent (licensing) regulatory requirements

CDPH/DHCS Antipsychotic Collaborative Executive Report

- Investigative findings demonstrated opportunity for improvement as related to:
  - Provision of accurate/complete information during informed consent process
  - Ensuring consideration of non-pharmacologic alternatives and risk vs. benefit prior to initiating antipsychotics
  - Development and implementation of complete/accurate antipsychotic care plans
  - Provision of quality consultant pharmacist services
    - Under licensing and federal regulatory requirements the consultant pharmacist is retained to ensure quality of pharmaceutical services

CDPH/DHCS Antipsychotic Collaborative Executive Report

- Summary of recommendations for improving NH antipsychotic use:
  - Enforcement
    - Develop a survey tool to evaluate appropriate antipsychotic use
      - Including informed consent, care planning and provision of consultant pharmacist services
    - Develop/implement methodology for identifying facilities with high rate of antipsychotic use
  - Education
    - Antipsychotic collaborative findings have been shared with stakeholders and organizations
      - CMS Region IX and CO, CAHF, CANHR, HSAG, DOJ, BoP, CalTCM, DHCS, CPhA, ASCP and others
      - Next steps: CDPH working with stakeholders to develop educational materials (stakeholder workgroup)

National Focus on Antipsychotic Medications

- HHS-OIG report released 5/2011 entitled "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents"
- Study conducted 1/1/07 – 6/30/07
- Findings: 22% of atypical antipsychotics prescribed in LTCs not administered in accordance with CMS standards
- Findings: 83% of antipsychotics prescribed in LTCs for off-label indication (dementia)

National Focus on Antipsychotic Medications

- CMS National Initiative to improve dementia care -- rolled out May 2012
  - Reduce NH antipsychotic use by 15%
  - Target date: end of 2012
  - Focus on non-pharmacologic interventions
  - "Nursing Home Compare" website will post MDS 3.0 Quality Measure antipsychotic use data July 2012
    - Indicator: Psychoactive Medication Use in Absence of Psychotic or Related Condition (long stay residents)

Antipsychotic Use Survey Tool

- Reflects federal regulatory requirements at F222, F329, F428, F501, F520 and others
- Reflects licensing regulatory requirements under informed consent and care planning
  - Reminder: separate 2567 must be generated when licensing deficiencies are written
- To be implemented during federal re-certification surveys and complaint investigations
- Should be utilized (along with pertinent survey notes) to assess appropriateness of antipsychotic use

Antipsychotic Use Survey Tool – Sample Selection for Use

- CMS to provide MDS 3.0 QM data on "Nursing Home Compare" website by 7/19/12: (http://www.medicare.gov/NHCompare/Include/DataSection/Questions/ProximitySearch.asp?bhcp=1)
- Facilities triggering 30% percent or more under QM indicator "Psychoactive Medication Use in Absence of Psychotic or Related Condition" (long stay residents):
  - Pre-select two residents receiving antipsychotics for Phase 1 review and use the survey tool for Sub-Task 5C Resident Review
- All other re-certification surveys:
  - Use the survey tool for sampled residents receiving antipsychotics during Sub-Task 5C Resident Review
- Federal complaint investigations related to residents receiving antipsychotic medications:
  - Use the survey tool

Antipsychotic Use Survey Tool – Step by Step

- **Section 1**: Primary indication(s) from the clinical record related to use of the antipsychotic medication (items 1 – 13)

1. Schizophrenia
2. Schizo-affective disorder
3. Delusional disorder
4. Mood disorders (e.g., bipolar disorder, depression w/ psychotic features
5. Schizophreniform disorders
6. Psychosis
7. Atypical Psychosis
8. Brief psychotic disorder
9. Dementing illnesses with associated behavioral symptoms
10. Medical illnesses with psychotic symptoms (e.g., neoplastic disease) and/or treatment related psychosis or mania (e.g., high dose steroids)
11. Tourette's Disorder or Huntington's disease
12. Hiccups or nausea and vomiting associated with cancer or chemotherapy
13. None of the above
    - Guidance indicates: if "Y" to any indications 1-10 complete Sections 2 - 4; if "Y" to 11 or 12 skip Sections 2 - 4 and continue with Section 5; if "Y" to 13 cite F329 (inadequate indication for use) or F222 (chemical restraints) and continue with Section 5.

Antipsychotic Use Survey Tool – Step by Step

- **Section 2**: Behavioral symptoms (one criteria must be met)
  - The symptoms are due to mania or psychosis (such as auditory, visual or other hallucinations; delusions); **OR**
  - The behavioral symptoms present a danger (documented to the resident or to others; **OR**
  - The symptoms are significant enough that the resident is experiencing one or more of the following:
    - Inconsolable or persistent distress (e.g., fear, continuously yelling, screaming, distress associated w/ end-of-life, or crying); **OR**
    - A significant decline in function; **OR**
    - Substantial difficulty receiving needed care (e.g., not eating resulting in weight loss; fear and not bathing leading to skin breakdown or infection).
  - Guidance indicates: cite at F329 (inadequate indication for use) or F222 (chemical restraints) if "N" response to all of the above

Antipsychotic Use Survey Tool – Step by Step

- **Section 3**: Chronic or Acute Psychiatric Condition
  - **3A**: Chronic condition (N/A if resident admitted on an antipsychotic):
    - Target behavior must be specifically identified and monitored objectively and quantitatively prior to medication use to ensure behavioral symptoms are:
      - Not due to medical condition and environmental/psychological stressors; and are persistent; and documented non-pharmacological interventions have been attempted but failed to resolve cause of the behaviors.

Antipsychotic Use Survey Tool – Step by Step

- **Section 3 (cont'd)**: Chronic or Acute Psychiatric Condition
  - **3B**: Acute situation/emergency:
    - Must meet identified criteria and be related to one/more clinical conditions in Section 1.
    - Acute treatment period is limited to 7 days/less; and a clinician (w/ IDT) must evaluate condition to identify/address underlying causes of acute condition and verify continuing need for medication; and non-pharmacological interventions must be attempted, unless contraindicated, and documented following the resolution of the acute psychiatric situation.

    - Guidance indicates: cite at F329 (inadequate indication/monitoring) or F222 if "N" response to any criteria under 3A or 3B. Additionally, if the facility failed to monitor the behaviors in an objective and quantitative manner, cite at F329 (for inadequate monitoring).

Antipsychotic Use Survey Tool – Step by Step

- **Section 4**: Dosage
  - If the antipsychotic is used to treat behavior symptoms associated with a dementing illness, the dosage does not exceed that listed in F329 (Table 1).
    - See supplemental guidance document
  - Resident is receiving one antipsychotic medication
  - Guidance indicates: cite at F329 (in excessive dosage or duplicate therapy) if "N" response to either of the above unless the prescriber has documented resident specific clinical rationale/justification demonstrating the benefit exceeds the associated risk.

Antipsychotic Use Survey Tool – Step by Step

- **Section 5**: Monitoring for Effectiveness
  - Target behaviors (for the antipsychotic medication) are:
    - Identified in the resident's care plan; monitored objectively and quantitatively; and
    - Consistent with the primary indication for use.
  - Behavioral data are:
    - Made available to the prescriber in a consolidated manner monthly; and
    - Sufficient to provide the prescriber with the necessary information to determine antipsychotic medication effectiveness/ineffectiveness as well as the presence of adverse consequences.
  - Guidance indicates: cite at F329 (inadequate monitoring) and/or F279 (care planning) if "N" response to any of the above.
    - Cite at Title 22 Section 72319(j)(2) and 72311(a)(1) if nursing care plan does not specify data to the collected for use in evaluating effectiveness and occurrence of adverse reactions; and/or
    - Cite Title 22 Section 72319(j)(3) if consolidated monthly behavioral data not available to the prescriber.

Antipsychotic Use Survey Tool – Step by Step

- **Section 6**: Monitoring for Adverse Consequences:
  - Adverse consequences to be monitored shall include at least the following:
    - Significant/severe consequences such as those listed in FDA boxed warnings (manufacturer's package insert) and those that may be significant based on the resident's clinical condition.
      - See electronic URLs in supplemental guidance: **http://www.fda.gov/Drugs/default.htm** and **https://blackboxrx.com/**
    - Those listed in Table 1 of F329 (also in supplemental guidance)
    - The associated adverse consequences are identified in the resident's care plan.
  - If the resident has experienced any possible/actual antipsychotic- related consequences the facility has documented such and taken action.
  - Guidance indicates: cite at F329 (inadequate monitoring or presence of adverse consequences which indicate the dose should be reduced or discontinued) if "N" response to any of the above.

Antipsychotic Use Survey Tool – Step by Step

- **Section 7**: Gradual Dose Reduction:
  - If the antipsychotic was initiated within the last year the facility has attempted a GDR in two separate quarters.
    - Must be at least one month between attempts
  - If the resident has been receiving the antipsychotic for more than one year the GDR has been attempted annually.
  - If no antipsychotic GDR has been attempted the prescriber has documented a taper is clinically contraindicated.
    - F329 GDR language is included in supplemental guidance
  - Guidance indicates cite at F329 (for excessive duration/GDR) if "N" response to any of the above.

Antipsychotic Use Survey Tool – Step by Step

- **Section 8**: Provision of Consultant Pharmacist Services:
  - Documentation is present the resident's clinical record was reviewed monthly by a consultant pharmacist.
  - If non-compliances related to antipsychotic use were noted in Sections 1 – 7 the consultant pharmacist identified irregularities in writing to the attending physician and director of nursing.
  - If the consultant pharmacist **did** identify (in the monthly Medication Regimen Review report) irregularities related to antipsychotic inappropriateness the facility acted on the report.
  - Guidance indicates cite at F428 (Medication Regimen Review) if "N" response to any of the above.

Antipsychotic Use Survey Tool – Step by Step

- **Section 9**: Informed Consent (RP = Responsible Party):
  - If the antipsychotic was initiated **prior** to admission to the facility the clinical record contains documentation of previous informed consent; or verification of resident consent after admission.
    - Guidance indicates cite T22 Section 72528(c) if "N" response
  - If the antipsychotic was initiated **after** admission to the facility the clinical record contains verification of resident informed consent. Exception is use for an emergency basis as defined in T22 Section 72528(e).
    - Guidance indicates cite T22 Section 72528(c) if "N" response
  - If the antipsychotic dosage was increased the clinical record contains verification of resident informed consent.
    - Guidance indicates cite H & SC Section 1418.9 if "N" response

Antipsychotic Use Survey Tool – Step by Step

- **Section 9**: Informed Consent (continued):
  - Interview the resident (or RP if the resident does not have capacity) to determine if the prescribing physician provided the following material information prior to the use of the antipsychotic:

1. The reason for the treatment and the nature and seriousness of the resident's illness; and
2. The nature of the proposed treatment including frequency and duration; and
3. The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment; and
4. The nature, degree, duration and probability of side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions; and
5. The reasonable alternative treatments and risks, and why the health professional is recommending the particular treatment; and
6. That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

  - Guidance indicates cite T22 Section 72528(b)(1-6) if "N" response to any of the above.

Antipsychotic Use Survey Tool – Step by Step

- **Section 9**: Informed Consent (continued):

  - Determine the prescribing physician provided material information necessary to obtain informed consent and received consent from the resident.
    - Guidance indicates cite T22 Section 72528(a) and/or H&SC 1418.9 if "N" response
  - Prior to giving informed consent, the information provided was understood and questions were satisfactorily answered.
    - Guidance indicates cite F156 if "N" response
  - The resident/RP has been invited to participate in care planning as it relates to the use of the antipsychotic medication.
    - Guidance indicates cite F280 or T22 Section 72527(a)(3) if "N" response

Antipsychotic Use Survey Tool – Step by Step

- **Section 9**: Informed Consent (continued):
  - If the resident does **not** have capacity to give informed consent and has **no** designated RP/person with legal authority to make those decisions on behalf of the resident:
    - The attending physician has identified efforts (resident interview/family members consulted, etc.) no person with legal authority exists.
    - The facility IDT has documented review, assessment and care planning (unless in an emergency) of the proposed antipsychotic order in accordance with H&SC 1418.8(e)(1) through (e)(6) prior to receipt of the medication.
    - In the case of an emergency antipsychotic medication intervention, the IDT has met within one week for an evaluation of the intervention.
    - The IDT has (at least quarterly or upon a significant change of condition) evaluated the antipsychotic therapy.
  - Guidance indicates cite H&SC 1418.8 if "N" response.

Antipsychotic Use Survey Tool – Step by Step

- **Section 9**: Informed Consent (continued):
  - Determine the following regarding informed consent policies and procedures:
    - The facility as written patients' rights policies and procedures related to psychotherapeutic informed consent.
    - Licensed nursing staff are familiar with written informed consent facility policies and procedures and are able to explain the process of verifying psychotherapeutic informed consent.
    - The resident's attending physician has verified (on interview) that antipsychotic informed consent was obtained in accordance with facility policies and procedures and regulatory requirements.
  - Guidance indicates cite T22 Section 72527(a) if "N" response to any of the above.

Antipsychotic Use Survey Tool – Step by Step

- **Section 9**: Informed Consent (continued):
  - The surveyor should consider issuance of a civil money citation for one or more of the following non-compliance(s):
    - Resident/RP indicates (on interview) required material information (as defined in T22 Section 72528 (1-6)) was not received in order to make an informed consent decision prior to receipt of the antipsychotic medication; and/or
    - Physician did not obtain informed consent from the resident (the process of informed consent was delegated to licensed nursing staff, ward clerk, etc.); and/or
    - Facility failed to develop and implement patients' rights policies and procedures, in accordance with state laws and regulations, related to psychotherapeutic informed consent.

Antipsychotic Use Survey Tool – Step by Step

- **Section 10**: Medical Director/Quality Assessment and Assurance (QAA):
  - Medical Director has ensured resident care policies and procedures were developed and implemented regarding antipsychotic informed consent.
  - Medical Director has addressed facility-identified clinically inappropriate use of antipsychotic medications in the context of regulatory requirements and current standards of practice.
  - QAA has developed and implemented an action plan related to non-compliances with antipsychotic informed consent; appropriate antipsychotic use; or acting on consultant pharmacist MRR recommendations related to inappropriate antipsychotic use (note: facility not required to disclose QAA minutes).
    - Guidance indicates cite F501 if "N" response to any of the first two items (Medical Director is responsible for implementation of resident care policies and/or the coordination of medical care in the facility); cite F520 if "N" response to the last item (QAA committee develops and implements appropriate plans of action to correct identified quality deficiencies).

Antipsychotic Use Survey Tool: In Summary

So what does this "Antipsychotic Survey Tool" help you do? It helps you determine the following:

1. Is there an appropriate indication for use of the antipsychotic (diagnosis and behavioral indication)?

2. Is there adequate monitoring related to antipsychotic use (effectiveness and adverse consequences)?

3. Is the dosage and duration of use appropriate?

4. Was informed consent obtained?

5. Is the consultant pharmacist actively involved in antipsychotic medication management?

6. Is the facility Medical Director overseeing the quality of care related to antipsychotic medication use?

7. Are there issues related to antipsychotic use which should be brought forward for the facility's Quality Assessment & Assurance (QAA) committee to address?

Contact Information

- If you have questions or comments related to the Antipsychotic Use Survey Tool or Supplemental Guidance, please contact:

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Thank you – questions?