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Committee on Children and Seniors
March 20, 2018
HB 2704
Written Testimony Opposed to HB 2704 - *Requiring written informed consent before administering an antipsychotic medication to an adult care home resident*

Chairwoman Davis and Members of the Committee:

My name is Vicki Whitaker, and I'm the executive director of the Kansas Association of Osteopathic Medicine (KAOM). Thank you for the opportunity to provide written comments to the Committee on Children and Seniors in opposition to House Bill 2704, an act concerning adult care homes; requiring written informed consent before administering an antipsychotic medication to an adult care home resident.

The Kansas Association of Osteopathic Medicine recognizes the intent of this bill is to reduce the use of antipsychotic medications in the elderly who reside in adult care homes. However, KAOM does not think HB 2704 will achieve this goal. The effect of this bill will be a greater burden of paperwork not better care. The requirements contained in the bill are already in the code of federal regulations.

An abstract from the National Institutes of Health, *Use of Antipsychotic Drugs by Elderly Primary Care Patients and the Effects of Medication Reviews: A Cross-Sectional Study in Sweden*, (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5567456/) details the issue. The study cited reviewed the use of antipsychotics in nursing home residents and a small sample of elderly receiving in-home care. The conclusions of the study were the excessive use of antipsychotics in the elderly could be reduced through medication reviews by a pharmacist through consultation with those caring for the residents. The study concluded some reduction in the use of antipsychotics could be achieved through a team approach. KAOM references this study because it recognizes the use of antipsychotics in the elderly in adult care homes is problematic not just in the United States but around the developed world. The completion of additional forms and paperwork will not solve the problem, it will only add additional time spent on paperwork for facility staff and the prescribing physicians.

The federal long term care facility regulations already address the use of antipsychotic medications and documentation with lengthy guidance and requirements including documentation (CFR 483.25 (l) Unnecessary Drugs: https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/downloads/som107ap_pp_guidelines_ltcf.pdf Federal regulations also require a pharmacist to review all residents medications on a monthly basis.

KAOM believes the additional paperwork which will result from HB 2704 will have unintended consequences such as more time spent on ensuring the most current form is used, the additional forms are placed in residents' charts, and time spent trying to arrange a time when the medical director or prescribing physician can meet with the resident or the resident's family member. A more effective solution would be to identify nursing facilities which have low usage of antipsychotics and share how these facilities achieve this goal – Best Practices. Training of surveyors and nursing facility staff on best practices has been done in the past and should be done on this important issue.

Thank you for the opportunity to comment on HB 2704 on behalf of osteopathic physicians who serve as medical directors or see residents in adult care homes in Kansas.

psychotropic medication and consider whether or not the medication can be reduced or discontinued upon admission or soon after admission. Additionally, the facility is responsible for:

- *Preadmission screening for mental illness and intellectual disabilities, see §483.20(k), F645 and F646; and*
- *Obtaining physician's orders for the resident's immediate care, see §483.20(a), F635.*

Monitoring of Psychotropic Medications: *When monitoring a resident receiving psychotropic medications, the facility must evaluate the effectiveness of the medications as well as look for potential adverse consequences. After initiating or increasing the dose of a psychotropic medication, the behavioral symptoms must be reevaluated periodically (at least during quarterly care plan review, if not more often) to determine the potential for reducing or discontinuing the dose based on therapeutic goals and any adverse effects or functional impairment.*

If the record shows evidence of adding other psychotropic medications or switching from one type of psychotropic medication to another category of psychotropic medication, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale.

Potential Adverse Consequences: *The facility assures that residents are being adequately monitored for adverse consequences such as:*

- ***General****: anticholinergic effects which may include flushing, blurred vision, dry mouth, altered mental status, difficulty urinating, falls, excessive sedation, constipation*
- ***Cardiovascular:*** *signs and symptoms of cardiac arrhythmias such as irregular heart beat or pulse, palpitations,lightheadedness, shortness of breath, diaphoresis, chest or arm pain, increased blood pressure, orthostatic hypotension*
- ***Metabolic:*** *increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain*
- ***Neurologic:*** *agitation, distress, EPS, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia, cerebrovascular event (e.g., stroke, transient ischemic attack (TIA).*

If the psychotropic medication is identified as possibly causing or contributing to adverse consequences as identified above, the facility and prescriber must determine whether the medication should be continued and document the rationale for the decision. Additionally, the medical record should show evidence that the resident, family member or representative is aware of and involved in the decision. In some cases, the benefits of treatment may outweigh the risks or burdens of treatment, so the medication may be continued.

Antipsychotic Medications

As with all medications, the indication for any prescribed first generation (also referred to as typical or conventional antipsychotic medication) or second generation (also referred to as atypical antipsychotic medication) antipsychotic medication must be thoroughly documented in the medical record. While antipsychotic medication may be prescribed for expressions or indications of distress, the IDT must first identify and address any medical, physical, psychological causes, and/or social/environmental triggers. Any prescribed antipsychotic

medication must be administered at the lowest possible dosage for the shortest period of time and is subject to the GDR requirements for psychotropic medications.

Antipsychotic medications (both first and second generation) have serious side effects and can be especially dangerous for elderly residents. When antipsychotic medications are used without an adequate rationale, or for the sole purpose of limiting or controlling expressions or indications of distress without first identifying the cause, there is little chance that they will be effective, and they commonly cause complications such as movement disorders, falls with injury, cerebrovascular adverse events (cerebrovascular accidents (CVA, commonly referred to as stroke), and transient ischemic events) and increased risk of death. The FDA Boxed Warning which accompanies second generation anti-psychotics states, "Elderly patients with dementia-related psychosis treated with atypical anti-psychotic drugs are at an increased risk of death," https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm. The FDA issued a similar Boxed Warning for first generation antipsychotic drugs, https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm. .

Diagnoses alone do not necessarily warrant the use of an antipsychotic medication. Antipsychotic medications may be indicated if:

- *behavioral symptoms present a danger to the resident or others;*
- *expressions or indications of distress that cause significant distress to the resident;*
- *If not clinically contraindicated, multiple non-pharmacological approaches have been attempted, but did not relieve the symptoms which are presenting a danger or significant distress; and/or* [34]
- *GDR was attempted, but clinical symptoms returned.*

If antipsychotic medications are prescribed, documentation must clearly show the indication for the antipsychotic medication, the multiple attempts to implement care-planned, non-pharmacological approaches, and ongoing evaluation of the effectiveness of these interventions.

Gradual Dose Reduction for Psychotropic Medications

The requirements underlying this guidance emphasize the importance of seeking an appropriate dose and duration for each medication and minimizing the risk of adverse consequences. The purpose of tapering a medication is to find an optimal dose or to determine whether continued use of the medication is benefiting the resident. Tapering may be indicated when the resident's clinical condition has improved or stabilized, the underlying causes of the original target symptoms have resolved, and/or non-pharmacological approaches have been effective in reducing the symptoms.

There are various opportunities during the care process to evaluate the effects of medications on a resident's physical, mental, and psychosocial well-being, and to consider whether the

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34 Steinberg, M., Lyketsos, C.G. (2012). Atypical antipsychotic use in patients with dementia: managing safety concerns. The American Journal of Psychology, 169, pp. 900-906. Retrieved from http://ajp.psychiatryonline.org/doi/full/10.1176/appi.ajp.2012.12030342.

Medication	Issues and Concerns
• pramipexole MAO inhibitors, e.g., • selegiline Others, e.g., • amantadine Various dopaminergic combinations, e.g., • carbidopa/levodopa • carbidopa/levodopa/ entacapone	
Antipsychotic medications	
All classes, e.g., First generation (conventional) agents, e.g. • chlorpromazine • fluphenazine • haloperidol • loxapine • mesoridazine • molindone • perphenazine • promazine • thioridazine • thiothixene • trifluoperazine • triflupromazine Second generation (atypical) agents, e.g. • aripiprazole • clozapine • olanzapine • quetiapine • risperidone • ziprasidone	**Indications** • An antipsychotic medication should be used only for the following conditions/diagnoses as documented in the record and as meets the definition(s) in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Training Revision (DSM-IV TR) or subsequent editions): o Schizophrenia o Schizo-affective disorder o Delusional disorder o Mood disorders (e.g. mania, bipolar disorder, depression with psychotic features, and treatment refractory major depression) o Schizophreniform disorder o Psychosis NOS o Atypical psychosis o Brief psychotic disorder o Dementing illnesses with associated behavioral symptoms o Medical illnesses or delirium with manic or psychotic symptoms and/or treatment-related psychosis or mania (e.g.,

Medication	Issues and Concerns
	thyrotoxicosis, neoplasms, high dose steroids) • In addition, the use of an antipsychotic must meet the criteria and applicable, additional requirements listed below: 1. Criteria: o Since diagnoses alone do not warrant the use of antipsychotic medications, the clinical condition must also meet at least one of the following criteria (A or B or C): A. The symptoms are identified as being due to mania or psychosis (such as: auditory, visual, or other hallucinations; delusions (such as paranoia or grandiosity)); OR B. The behavioral symptoms present a danger to the resident or to others; OR C. 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 with end-of-life, or crying); a significant decline in function; and/or substantial difficulty receiving needed care (e.g., not eating resulting in weight loss, fear and not bathing leading to skin breakdown or infection). 2. Additional Requirements: o Acute Psychiatric Situations When an antipsychotic medication is being initiated or used to treat an acute psychiatric emergency (i.e., recent or abrupt onset or exacerbation of symptoms) related to one or more of the aforementioned conditions/diagnoses, that use must meet one of the above criteria and all of the following additional

Medication	Issues and Concerns
	requirements: A. The acute treatment period is limited to seven days or less; and B. A clinician in conjunction with the interdisciplinary team must evaluate and document the situation within 7 days, to identify and address any contributing and underlying causes of the acute psychiatric condition and verify the continuing need for antipsychotic medication; and C. Pertinent non-pharmacological interventions must be attempted, unless contraindicated, and documented following the resolution of the acute psychiatric situation. o Enduring Psychiatric Conditions Antipsychotic medications may be used to treat an enduring (i.e., non-acute, chronic, or prolonged) condition, if the clinical condition/diagnosis meets the criteria in #1 above. In addition, before initiating or increasing an antipsychotic medication for enduring conditions, the target behavior must be clearly and specifically identified and monitored objectively and qualitatively, in order to ensure the behavioral symptoms are: A. Not due to a medical condition or problem (e.g., headache or joint pain, fluid or electrolyte imbalance, pneumonia, hypoxia, unrecognized hearing or visual impairment) that can be expected to improve or resolve as the underlying condition is treated; and B. Persistent or likely to reoccur without continued treatment; and C. Not sufficiently relieved by non-

Medication	Issues and Concerns
	pharmacological interventions; and D. Not due to environmental stressors (e.g., alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for that individual, inadequate or inappropriate staff response, physical barriers) that can be addressed to improve the psychotic symptoms or maintain safety; and E. Not due to psychological stressors (e.g., loneliness, taunting, abuse), or anxiety or fear stemming from misunderstanding related to his or her cognitive impairment (e.g., the mistaken belief that this is not where he/she lives or inability to find his or her clothes or glasses) that can be expected to improve or resolve as the situation is addressed • After initiating or increasing the dose of an antipsychotic medication, the behavioral symptoms must be reevaluated periodically to determine the effectiveness of the antipsychotic and the potential for reducing or discontinuing the dose **Exception:** When antipsychotic medications are used for behavioral disturbances related to Tourette's disorder, or for non-psychiatric indications such as movement disorders associated with Huntington's disease, hiccups, nausea and vomiting associated with cancer or cancer chemotherapy, or adjunctive therapy at end of life. **Inadequate Indications** • In many situations, antipsychotic medications are not indicated. They should not be used if the only indication is one or more of the following: 1) wandering; 2) poor self-care; 3) restlessness; 4) impaired memory; 5) mild anxiety; 6) insomnia; 7) unsociability; 8) inattention or indifference to

<table>
<tr><th>Medication</th><th>Issues and Concerns</th></tr>
<tr><td></td><td>surroundings; 9) fidgeting; 10) nervousness; 11) uncooperativeness; or 12) verbal expressions or behavior that are not due to the conditions listed under "Indications" and do not represent a danger to the resident or others.</td></tr>
<tr><td></td><td>
Dosage
Doses for acute indications (for example, delirium) may differ from those used for long-term treatment, but should be the lowest possible to achieve the desired therapeutic effects
Daily Dose Thresholds for Antipsychotic Medications Used to Manage Behavioral Symptoms Related to Dementing Illnesses
<table>
<tr><th>Generic Medication</th><th>Dosage</th></tr>
<tr><td colspan="2">First Generation</td></tr>
<tr><td>chlorpromazine</td><td>75 mg</td></tr>
<tr><td>fluphenazine</td><td>4 mg</td></tr>
<tr><td>haloperidol</td><td>2 mg</td></tr>
<tr><td>loxapine</td><td>10 mg</td></tr>
<tr><td>molindone</td><td>10 mg</td></tr>
<tr><td>perphenazine</td><td>8 mg</td></tr>
<tr><td>pimozide</td><td>*</td></tr>
<tr><td>prochloroperazine</td><td>*</td></tr>
<tr><td>thioridazine</td><td>75 mg</td></tr>
<tr><td>thiothixene</td><td>7 mg</td></tr>
<tr><td>trifluoperazine</td><td>8 mg</td></tr>
<tr><td colspan="2">Second Generation</td></tr>
<tr><td>aripiprazole</td><td>10 mg</td></tr>
<tr><td>clozapine</td><td>50 mg</td></tr>
<tr><td>olanzapine</td><td>7.5 mg</td></tr>
<tr><td>quetiapine</td><td>150 mg</td></tr>
<tr><td>risperidone</td><td>2 mg</td></tr>
<tr><td>ziprasidone</td><td>*</td></tr>
</table>
* Not customarily used for the treatment of behavioral symptoms

References:

Katz, I.R. (2004). Optimizing atypical antipsychotic treatment strategies in the elderly. Journal of the American Geriatrics Society, 52, pp. 272-277.
</td></tr>
</table>

Medication	Issues and Concerns
	Schneider, L.S. (2005). Risk of death with atypical antipsychotic drug treatment for dementia. Meta-analysis of randomized placebo controlled trials. Journal of the American Medical Association, 294, pp. 1934-1943. Saltz, B.L., Woerner, M.G., Robinson, D.G., & Kane, J.M. (2000). Side effects of antipsychotic drugs: Avoiding and minimizing their impact in elderly patients. Postgraduate Medicine, 107, pp. 169-178.
	Duration • If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance
	Monitoring/Adverse Consequences • The facility assures that residents are being adequately monitored for adverse consequences such as: o anticholinergic effects (see Table II) o akathisia o neuroleptic malignant syndrome (NMS) o cardiac arrhythmias o death secondary to heart-related events (e.g., heart failure, sudden death) o falls o lethargy o increase in total cholesterol and triglycerides o parkinsonism o blood sugar elevation (including diabetes mellitus) o orthostatic hypotension o cerebrovascular event (e.g., stroke, transient ischemic attack (TIA)) in older individuals with dementia o tardive dyskinesia o excessive sedation • When antipsychotics are used without monitoring

End →

Medication	Issues and Concerns
	they may be considered unnecessary medications because of inadequate monitoring.
Anxiolytics	
All Anxiolytics Benzodiazepines, Short-acting, e.g., • alprazolam • estazolam • lorazepam • oxazepam • temazepam Benzodiazepines, Long acting, e.g., • chlordiazepoxide • clonazepam • clorazepate • diazepam • flurazepam • quazepam buspirone Other antidepressants except bupropion	**Indications** • Anxiolytic medications should only be used when: o Use is for one of the following indications as defined in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Training Revision (DSM-IV TR) or subsequent editions: a. Generalized anxiety disorder b. Panic disorder c. Symptomatic anxiety that occurs in residents with another diagnosed psychiatric disorder d. Sleep disorders (See Sedatives/Hypnotics) e. Acute alcohol or benzodiazepine withdrawal f. Significant anxiety in response to a situational trigger g. Delirium, dementia, and other cognitive disorders with associated behaviors that: – Are quantitatively and objectively documented; – Are persistent; – Are not due to preventable or correctable reasons; and – Constitute clinically significant distress or dysfunction to the resident or represent a danger to the resident or others • Evidence exists that other possible reasons for the