

Submitted electronically

September 16, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3347-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: [CMS-3347-P] Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions To Promote Efficiency, and Transparency

The undersigned organizations are writing with our response to the Centers for Medicare & Medicaid Services' (CMS) proposed decision on Medicare and Medicaid program requirements for long-term care facilities. Collectively, our organizations represent constituencies of geriatric psychiatrists, geriatricians and gerontologists, consultant pharmacists, family caregivers, older adults, and advocates for minority health.

We applaud CMS for its efforts to remove unnecessary, obsolete, and excessively burdensome medication requirements, particularly in regards to the section in the proposed rule titled "Proposed Changes to Pharmacy Services (§ 483.45)." We support CMS' proposed changes for 'Pro re Nata' (PRN) antipsychotics and believe these changes will improve care by enabling health care professionals to better use their time attending to the needs of residents rather than on administrative tasks. However, there is more CMS can do to ensure the appropriate use of antipsychotics and other psychotropic medications for people with dementia. We outline our recommendations below.

Unmet Medical Need for Behavioral and Neuropsychiatric Symptoms (NPS) in Dementia

There is a large unmet medical need in long-term care settings for the diagnosis and management of behavioral and neuropsychiatric symptoms (NPS) in dementia, including: wandering, sleep issues, agitation, depression, apathy, aggression, and psychosis. Effectively managing or preventing behaviors that disturb and can cause harm to self and others is valuable to residents, family caregivers, and payers. While cognitive impairment is regarded as the hallmark indicator of dementia, NPS are nearly as universal, with one or more symptoms affecting nearly all people with dementia over the illness course.¹ The recognition of NPS as the expression of neurological disease results in the inclusion of NPS in the diagnosis of dementia.²

Among people with Alzheimer's disease (AD), depression is the earliest observable symptom in at least one-third of cases.³ Milder agitation may manifest early and increase in prevalence and severity with worsening of dementia, often leading to an increase in caregiver burden, greater morbidity, poorer quality of life, increased cost of care, early institutionalization, and rapid disease progression.⁴ For long-term care staff caring for residents

¹ Kales HC, Gitlin LN, Lyketsos CG. State of the Art Review: Assessment and management of behavioral and psychological symptoms of dementia. *BMJ* 2015;350:h369.

² Cummings J, Ritter A, Rothenburg K. Advances in Management of Neuropsychiatric Syndromes in Neurodegenerative Diseases. *Curr Psychiatry Rep* 2019; 21:79, published online August 8, 2019.

<https://link.springer.com/article/10.1007/s11920-019-1058-4>.

³ Masters MC, Morris JC, Roe CM. Noncognitive Symptoms of Early Alzheimer disease: A longitudinal analysis. *Neurology* 2015;84:617–622.

⁴ Smith Z, Smith EE, Geda Y, et al. Neuropsychiatric Symptoms as Early Manifestations of Emergent Dementia: Provisional diagnostic criteria for mild behavioral impairment. *Alzheimer's Dement* 2016; 12:195–202.

with depression, agitation, and other NPS, these disorders are associated with decreased quality of care, injury, increased workload, lost days of work, burnout, and staff turnover.^{5 6}

In the Summer of 2019, the American Association for Geriatric Psychiatry (AAGP)—in collaboration with American Psychiatric Association—conducted a survey of its members caring for older adults in long-term care settings (respondents=102). Key highlighted results reveal:

- 86% reported experiencing barriers to prescribing psychotropics appropriately for their patients due to policies that penalize such prescribing;
- 73% reported patients became destabilized, requiring more acute levels of care as a result of the failure to provide appropriate psychotropic medications due to policies limiting their use;
- 35% reported a portion of those destabilized patients treated in acute care settings were denied readmission to the long-term care facility; and
- 58% reported a facility staff member has requested that they alter their prescribing practices so the facility may achieve a higher quality rating score.

At the June 2019 American Medical Association (AMA) House of Delegates meeting in Chicago, IL, AAGP introduced resolution 708, “Access to Psychiatric Treatment in Long-Term Care.” The original resolution read:

- I. RESOLVED, That our American Medical Association ask the Centers for Medicare and Medicaid Services (CMS) to acknowledge that psychotropic medications can be an appropriate long-term care treatment for patients with chronic mental illness (Directive to Take Action); and be it further
- II. RESOLVED, That our AMA ask CMS to discontinue the use of psychotropic medication as a factor contributing to the Nursing Home Compare rankings, unless the data utilized is limited to medically inappropriate administration of these medications (Directive to Take Action); and be it further
- III. RESOLVED, That our AMA ask the CMS to acknowledge that antipsychotic medication can be an appropriate treatment for dementia-related psychosis if non-pharmacologic approaches have failed (Directive to Take Action); and be it further
- IV. RESOLVED, That our AMA ask CMS to refrain from issuing citations or imposing financial penalties for the medically necessary and appropriate use of antipsychotic medication for the treatment of dementia-related psychosis. (Directive to Take Action)

Testimony on Resolution 708, including from the Society delegation, was unanimously supportive with a number of delegates raising concerns of skilled nursing facilities denying admission to patients on antipsychotics for fear of being penalized and negative impact on Nursing Home Compare. In its testimony, the Council noted that Policy D-120.951 (Appropriate Use of Antipsychotic Medications in Nursing Home Patients), which passed the AMA in 2012, not only addresses the first, third, and fourth Resolve clauses but also is nearly identical language. However, the Council supported adoption of the second Resolve and recognized that the AMA’s lack of policy on the use of antipsychotic medication is a factor in Nursing Home Compare rankings. Testimony noted that current CMS policies on the use of antipsychotic medications may cause patient harm and urged AMA action on this issue. Resolution 708 was adopted as amended (to only include the second Resolved) and Policy D-120.951 reaffirmed.

⁵ Lachs MS, Rosen T, Teresi JA, et al. Verbal and Physical Aggression Directed at Nursing Home Staff by Residents. *J Gen Intern Med* 2013;28:660-667.

⁶ Zeller A, Hahn S, Needham I, et al. Aggressive Behavior of Nursing Home Residents Toward Caregivers: A systematic literature review. *Geriatr Nurs* 2009;30:174-187.

Specific diagnostic criteria have been developed for psychosis in AD⁷, depression in AD⁸, apathy in AD and other neurodegenerative disorders⁹, and agitation in cognitive disorders including AD.¹⁰ In Parkinson's disease (PD), criteria have been developed to include psychosis in PD¹¹ and depression in PD¹². Diagnostic criteria, combined with clinical guidelines, are essential to inform prescribers and to explain the use of the medication to patients, as well as professional and family caregivers. The need for pharmacologic intervention should ultimately be established on a case-by-case basis. This patient-centered approach allows the care team to consider comorbidities, acuity level, and many other personalized factors and would strengthen the meaning of the percentages in the two quality metrics. **CMS should consider better integration of diagnostic criteria and clinical guidelines into nursing home operator, medical director, nursing, and surveyor trainings, as well as in standardized patient assessment elements (SPADEs) for the Minimum Data Set (MDS), Outcome and Assessment Information Set (OASIS), Inpatient Rehabilitation Facility–Patient Assessment Instrument (IRF-PAI), and LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS), and our organizations are ready and willing to help with this effort.**

Clinical Management and Clinical Development for NPS in Dementia

While antipsychotics have been used to treat NPS since the 1950s, people with neurodegenerative disorders were previously excluded from trials of psychotropic medications in general, and antipsychotics specifically, despite the fact that both brain changes and biological aging may impact psychotropic dosage needs and response, carrying significant risks.

In April 2005, the FDA issued a "black-box" warning for atypical antipsychotics in the treatment of NPS in older patients with dementia because of a 1.6- to 1.7-fold higher death rate in those taking such drugs compared with those taking a placebo. In a pivotal randomized control trial (RCT) of demented patients already on conventional or atypical antipsychotics, 3-year survival doubled in those randomized to cease treatment.¹³ However, a large longitudinal observational study published in the September 2013 issue of the *American Journal of Psychiatry* challenged these findings by showing that **the primary correlate of adverse outcomes was the psychiatric symptomatology and not the drugs used to treat these symptoms.**¹⁴ Additionally, a 2015 study in the same journal analyzed data from the Cache County Dementia Progression Study to examine the link between clinically significant neuropsychiatric symptoms in mild Alzheimer's dementia and progression to severe dementia and death—the study found that psychosis (hazard ratio=1.537, p=0.011), affective symptoms (hazard ratio=1.510,

⁷ Jeste DV, Finkel SI. Psychosis of Alzheimer's Disease and Related Dementias: Diagnostic criteria for a distinct syndrome. *Am J Geriatr Psychiatry* 2000;8(1):29–34. <https://doi.org/10.1097/00019442-200002000-00004>.

⁸ Olin JT, Schneider LS, Katz IR, Meyers BS, Alexopoulos GS, Breitner JC, et al. Provisional Diagnostic Criteria for Depression of Alzheimer's Disease: Description and review. *Expert Rev Neurother* 2003;3(1):99–106. <https://doi.org/10.1586/14737175>.

⁹ Robert P, Onyike CU, Leentjens AF, Dujardin K, Aalten P, Starkstein S, et al. Proposed Diagnostic Criteria for Apathy in Alzheimer's disease and Other Neuropsychiatric Disorders. *Eur Psychiatry* 2009;24(2):98–104. <https://doi.org/10.1016/j.eurpsy.2008.09.001>.

¹⁰ Cummings J, Mintzer J, Brodaty H, Sano M, Banerjee S, Devanand DP, et al. Agitation in Cognitive Disorders: International Psychogeriatric Association provisional consensus clinical and research definition. *Int Psychogeriatr* 2015;27(1):7–17. <https://doi.org/10.1017/S1041610214001963>.

¹¹ Ravina B, Marder K, Fernandez HH, Friedman JH, McDonald W, Murphy D, et al. Diagnostic Criteria for Psychosis in Parkinson's Disease: Report of an NINDS, NIMH work group. *Mov Disord* 2007;22(8):1061–8. <https://doi.org/10.1002/mds.21382>.

¹² Marsh L, Williams JR, Rocco M, Grill S, Munro C, Dawson TM. Psychiatric Comorbidities in Patients with Parkinson Disease and Psychosis. *Neurology* 2004;63(2):293–300.

¹³ Maust DT, Kim H, Seyfried LS, et al. Antipsychotics, Other Psychotropics, and the Risk of Death in Patients with Dementia: Number needed to harm *JAMA Psychiatry* 2015;72:438–445.

¹⁴ Lopez OL, Becker JT, Chang YF, et al. The Long-Term Effects of Conventional and Atypical Antipsychotics in Patients with Probable Alzheimer's disease. *Am J Psychiatry* 2013;170:1051–8.

$p=0.003$), agitation/aggression (hazard ratio=1.942, $p=0.004$), mildly symptomatic neuropsychiatric symptoms (domain score of 1–3, hazard ratio=1.448, $p=0.024$), and clinically significant neuropsychiatric symptoms (hazard ratio=1.951, $p=<0.001$) were associated with earlier death.¹⁵ It is important to note that neurodegenerative disorders are progressive and fatal. The treatments for such diseases, whether pharmacologic or non-pharmacologic, are symptomatic only.

While no medication has been specifically approved at this time for the treatment of agitation in Alzheimer's disease or other NPS, a number of studies have been published with information strong enough to provide guidance to clinicians. For example, two studies with almost identical design have shown efficacy of methylphenidate in the treatment of apathy in Alzheimer's disease.^{16 17} With regards to the treatment of agitation, there is a large amount of literature clearly showing a small but consistent effect of atypical antipsychotics of the treatment of agitation in Alzheimer's disease and other dementias;¹⁸ and, studies have shown that citalopram and the combination of dextromethorphan and quinidine are safe and effective.^{19 20}

When the adequate population is targeted, the size of the effect is magnified and the safety profile improved. A study by Devonand, Mintzer, and others showed significant differences in relapse rates of symptoms of agitation in patients that responded to treatment with an atypical antipsychotic (risperidone).²¹ These results indicate the inappropriateness of discontinuing these medications after a patient has shown a clear symptomatic response. There are also non-antipsychotic options currently under development as potential alternatives.

Only one drug—pimavanserin—is currently approved by the U.S. FDA for the treatment of NPS in neurodegenerative disorders. This agent is approved for the treatment of hallucinations and delusions occurring in PD psychosis.²² All other use of psychotropics is “off label,” although it may be necessary for best practices, based on extensive experience, and endorsed by treatment guidelines.^{23 24}

¹⁵ Peters ME, Schwartz S, Han D, et al. Neuropsychiatric symptoms as predictors of progression to severe Alzheimer's dementia and death: The Cache County Dementia Progression Study. *Am J Psychiatry*. 2015 May 1; 172(5):460–465.

¹⁶ Padala, Prasad & Padala, Kalpana & Lensing, et al. Methylphenidate for Apathy in Community-Dwelling Older Veterans With Mild Alzheimer's Disease: A Double-Blind, Randomized, Placebo-Controlled Trial. *The American journal of psychiatry*. 2017;175. <https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2017.17030316>

¹⁷ Rosenberg PB, Lanctôt KL, Drye LT, et al. Safety and efficacy of methylphenidate for apathy in Alzheimer's disease: a randomized, placebo-controlled trial. *J Clin Psychiatry*. 2013;74(8):810–816.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3902018/>

¹⁸ Schneider LS, et al. "Effectiveness of Atypical Antipsychotic Drugs in Patients with Alzheimer's Disease". *The New England Journal of Medicine*. 2006. 355(15):1525-38.

¹⁹ Porsteinsson AP, Drye LT, Pollock BG, et al. Effect of citalopram on agitation in Alzheimer disease: the CitAD randomized clinical trial. *JAMA*. 2014;311(7):682–691. <https://www.ncbi.nlm.nih.gov/pubmed/24549548/>

²⁰ Jeffrey L. Cummings, MD, ScD; Constantine G. Lyketsos, MD, MHS; Elaine R. Peskind, MD; et al. Effect of Dextromethorphan-Quinidine on Agitation in Patients With Alzheimer Disease Dementia: A Randomized Clinical Trial, *JAMA*. 2015;314(12):1242-1254. <https://jamanetwork.com/journals/jama/fullarticle/2442936>

²¹ Devanand, et al. (2012). Relapse risk after discontinuation of risperidone in Alzheimer's disease. *The New England Journal of Medicine*, 367 16, 1497-507 .

²² Cummings J, Isaacson S, Mills R, Williams H, Chi-Burris K, CorbettA, et al. Pimavanserin for Patients with Parkinson's Disease Psychosis: A randomised, placebo-controlled phase 3 trial. *Lancet* 2014;383(9916):533–40. [https://doi.org/10.1016/S0140-6736\(13\)62106-6](https://doi.org/10.1016/S0140-6736(13)62106-6).

²³ Alexopoulos GS, Jeste DV, Chung H, Carpenter D, Ross R, Docherty JP. The EConsensus Guideline Series:Treatment of dementia and its behavioral disturbances. Introduction: methods, commentary, and summary. *Postgrad Med* 2005;Spec No:6–22.

²⁴ Kales HC, Gitlin LN, Lyketsos CG; Detroit Expert Panel on Management of Neuropsychiatric Symptoms of Dementia in Clinical Settings: Recommendations from a Multidisciplinary Expert Panel. *J Am Geriatr Soc*2014;62(4):762–9.

<https://doi.org/10.1111/jgs.12730>.

A recent *Current Psychiatry Reports* paper provides a comprehensive summary, with study citations, of recommended pharmacologic treatments for NPS:²⁵

Table 1 Recommended treatments for neuropsychiatric syndromes

Neuropsychiatric syndrome	1st-line therapies*	2nd-line therapies	3rd-line therapies
Agitation in AD	Citalopram (10–30 mg/day)** Risperidone (0.5–1 mg/day)	Aripiprazole (10 mg/day) Carbamazepine (300 mg/day) Dextromethorphan/quinidine (20/10 mg BID) Olanzapine (5–10 mg/day) Quetiapine (200 mg/day) Trazodone (50–100 mg/day) Modafinil (200 mg/day)	Lamotrigine (25–100 mg/day) THC (2.5–7 mg/day)
Apathy in AD	Methylphenidate (20 mg/day)		
Depression in AD	Citalopram (10–40 mg/day)** Escitalopram (5–20 mg) Sertraline (50–150 mg)	Aripiprazole as augmentation (2 mg–15 mg/day) Bupropion (100 mg–300 mg/day) Carbamazepine (augmentation) (300 mg/day) Duloxetine (20–60 mg/day) Fluoxetine (20–40 mg/day) Mirtazapine (7.5–30 mg/day) Paroxetine (10–40 mg/day) Quetiapine as augmentation (25–200 mg/day) Venlafaxine (37.5–225 mg/day)	Electroconvulsive therapy Tricyclic antidepressants
Depression in PD	Pramipexole (0.3–4.2 mg/day) Ropinirole (10 mg/day)	Citalopram (10–20 mg/day) Desipramine (25–75 mg/day)*** Nortriptyline (25–75 mg/day)*** Sertraline(25–50 mg/day)	Electroconvulsive therapy Bupropion (100–300 mg/day) Duloxetine (30–60 mg/day) Mirtazapine(30 mg/day) Paroxetine (10–40 mg/day) Venlafaxine (37.5–225 mg/day)
Psychosis in PD	Pimavanserin (40 mg/day)	Clozapine (6.25–50 mg/day) Quetiapine (25–100 mg/day)	Risperidone (0.5–2 mg/day) Olanzapine (5–7.5 mg/day)

*Initiation of pharmacological interventions should occur after non-pharmacological approaches, cognitive enhancers, and comprehensive assessment of medical and environmental factors has been completed

**Maximum recommended dose for citalopram in patients over the age of 60 is 20 mg/day

***TCA should not be used in patients with cognitive impairment

CMS currently identifies three appropriate indications for antipsychotic medication: Tourette's syndrome, schizophrenia and Huntington's chorea. However, there are three additional diagnoses that have FDA approved indications for the use of antipsychotic medications but are not currently included as appropriate by CMS: Parkinson's disease psychosis, major depression with psychosis and, bipolar disorder. Furthermore, clinical development will soon identify additional psychoactive medications indicated to treat or manage perceptual disturbances (hallucinations, paranoia and delusions), and behavioral disturbances (agitation and terminal restlessness), in patients who also carry a dementia diagnosis.

The chart below, also from the *Current Psychiatry Reports* paper, shows the robust pipeline of new treatments in development for the treatment of NPS. It is reasonable to expect that, given the FDA's acceptance of the recently crafted definitions of psychosis and agitation in dementia and the upcoming definition of apathy in dementia, several new treatments may be approved in the near future. This will be a rare opportunity for a "new start". When these treatments become available, it will be critical to implement education initiatives and new regulations will assure these new treatments are appropriately utilized. Many of the products in this pipeline are likely to reach the market within a short period of time and be more effective than existing therapy. **As CMS considers revising its policy regarding PRN antipsychotics, we ask that they consider the impact of the availability of these new products to long-term care residents.**

²⁵ Cummings J, Ritter A, Rothenburg K. Advances in Management of Neuropsychiatric Syndromes in Neurodegenerative Diseases. *Curr Psychiatry Rep* 2019; 21:79, published online August 8, 2019.
<https://link.springer.com/article/10.1007/s11920-019-1058-4>.

Table 2 Drugs in currently active double-blind placebo-controlled clinical trials for neuropsychiatric aspects of neurodegenerative disorders (from clinicaltrials.org; accessed May 21, 2018)

Disorder	Neuropsychiatric syndrome	Agent	Phase	Sponsor
Alzheimer's disease	Agitation	Gabapentin	4	University of Texas, Austin
	Agitation	Pimavanserin	2	ACADIA Pharmaceuticals
	Agitation	Dronabinol	2	Johns Hopkins University
	Agitation	AVP-786	3	Avanir Pharmaceuticals
	Agitation	Escitalopram	3	Johns Hopkins Bloomberg School of Public Health
	Agitation	Nabilone	3	Sunnybrook Health Sciences Center
	Agitation	Carbamazepine and mirtazapine	3	University of Success
	Agitation or psychosis	MP-101	2	Mediti Pharmaceuticals Inc
	Agitation	Lithium	2	New York State Psychiatric Institute
	Agitation (mild)	Piromelatine	2	Neurim Pharmaceuticals Ltd
Dementia with Lewy bodies	Apathy	Methylphenidate	3	Johns Hopkins Bloomberg School of Public Health
	Sleep	Zolpidem; zopiclone	3	Brasilia University Hospital
		Lemborexant	2	Eisai Inc.
		Suvorexant	3	Merck Sharp & Dohme Corp.
	REM Sleep Behavior Disorder	Nelotanserin	2	Axovant Sciences Ltd.
Parkinson's disease	Psychosis	SEP-363856	2	Sunovion
	REM Sleep Behavior Disorder	Nelotanserin	2	Axovant Sciences Ltd.
	REM Sleep Behavior Disorder	Melatonin and clonazepam	2	Seoul National University Hospital
	Excessive sleepiness	JZP-110	2	Jazz Pharmaceuticals
	Sleep disturbances	Melatonin	4	KIMJisun
Huntington's disease	Depression (inadequately controlled)	Pimavanserin	2	ACADIA Pharmaceuticals
	Impulse control disorder	N-acetylcysteine	3	Center Hospitaliere Universitaire, Amiens
	Irritable mood	SRX246	1/2	Azevan Pharmaceuticals
Dementia*	Psychosis	Pimavanserin	3	ACADIA Pharmaceuticals

*Dementia-related psychosis includes psychosis occurring in Alzheimer's disease, vascular dementia, frontotemporal dementia, progressive supranuclear palsy, and corticobasal degeneration

Real-World Implications of Current CMS Policy

To address the high use of antipsychotics in residents with dementia, CMS launched the National Partnership to Improve Dementia Care in Nursing Homes in 2012 to “improve the quality of care” for nursing home residents with dementia, primarily by achieving reductions in use of antipsychotics.²⁶ Also in 2012, the American Board of Internal Medicine initiated “Choosing Wisely,”²⁷ targeting “low-value care,” including the first-line use of antipsychotics for NPS. Since the establishment of these efforts, antipsychotic use has reportedly been significantly reduced by 39% among long-term care residents from 2009 to 2018.²⁸

²⁶ CMS announces partnership to improve dementia care. 2012. Available at: <https://www.cms.gov/newsroom/press-releases/cms-announces-partnership-improve-dementia-care-nursing-homes>.

²⁷ Choosing Wisely: A Special Report on the First Five Years. Available at: www.choosingwisely.org/choosing-wisely-a-special-report-on-the-first-five-years/?ve-things-physicians-and-patients-should-question-press-release-april-4-2012/

²⁸ Available at: https://www.nhqualitycampaign.org/files/AP_package_20180131.pdf.

In practice however, CMS' National Partnership effort includes only one quality measure related to dementia—the frequency of antipsychotic use, which CMS reports publicly through the Nursing Home Compare website and the Five-Star Quality Rating System for nursing homes. There exists no mechanism to adjust the quality metrics for antipsychotic use to the type of skilled nursing facility. Many skilled nursing facilities specialize in the care of older adults with psychosis. Many rural skilled nursing facilities admit residents with a higher percentage of psychosis than urban facilities. Because of the types of residents they accept, these facilities need to use antipsychotics at a higher rate. However, because *quality scores report only the frequency of use, these facilities are not being fairly assessed on the quality of care that they provide*. It can be unclear whether a poor score reflects poor resident care or merely the demographics of the resident population at a particular facility. Additionally, it creates incentives for these facilities to underutilize antipsychotics when their patients are in need and thus, potentially inducing harm and suffering.

The CMS requirements for use of antipsychotics based on the State Operations Manual (SOM) are also incongruent with the Five-Star Quality Rating System. The rating system requires that residents on antipsychotics have a diagnosis of Schizophrenia, Huntington's disease, or Tourettes Syndrome for their use to not negatively impact the building's five star rating score. Because five star is correlated with both admissions and reimbursements, buildings have a large incentive to obtain the highest rating possible. This results in several negative effects towards residents who have a history of psychiatric illness or have had positive benefit from the use of antipsychotic medication in the past. For example, a resident with Bipolar disorder may be admitted to the facility stable on antipsychotic medication, but the facility can provide pressure to the prescriber to change or discontinue the medication because of the impact on five star rating. It is important to note that this occurs even in cases where the medication is being used in a manner that is consistent with FDA approval and generally accepted standard of care. Residents with psychiatric illness are also more likely to have their medication discontinued in an effort to comply with the requirements of gradual dose reductions even if the medication is appropriate, effective, and not causing negative effects. *Psychiatric medications are the only class of medications identified by CMS for discontinuation trials even in the context of successful treatment. Unfortunately, when residents decompensate psychiatrically it is difficult if not impossible to stabilize them back to their predecompensation state. The result is a periodic decline in overall function occurring on a scheduled basis brought on by the facility's need to meet CMS requirements.*

CMS developed a training program and care plans to promote "person-centered high-quality care" and the use of non-pharmacologic treatment alternatives to antipsychotics.²⁹ Unfortunately, less than 2% of facilities consistently implement the person-centered care approaches for NPS³⁰ and most staff lack the knowledge, skills, or experience to effectively implement nonpharmacologic approaches.^{31 32} Such person-centered care requires resources and time, including reimbursement for implementation, and commitment to these goals.

Medication reconciliation has been identified as a major intervention to target and reduce the burden of medication discrepancies and medication errors during transitions in care.³³ Patients are vulnerable when

²⁹ Centers for Medicare & Medicaid Services. Person-centered care training. Available at:

<https://surveyortraining.cms.hhs.gov/pubs/HandinHand.aspx>

³⁰ Grabowski DC, O'malley AJ, Afendulis CC, et al. Culture Change and Nursing Home Quality of Care. *Gerontologist* 2014;54:S35-S45.

³¹ Kolanowski A, Van Haitsma K, Penrod J, et al. "Wish we would have known that!" Communication breakdown impedes person-centered care. *Gerontologist* 2015;55:S50-S60.

³² Marx KA, Stanley IH, Van Haitsma K, et al. Knowing Versus Doing: Education and training needs of staff in a chronic care hospital unit for individuals with dementia. *J Gerontol Nurs* 2014;40:26-34.

³³ Kostas T, Paquin AM, Zimmerman K et al. Characterizing medication discrepancies among older adults during transitions of care: a systematic review focusing on discrepancy synonyms, data sources and classification terms. *Aging Health*, 2013; 9: 497– 508.

admitted to, and discharged from, hospital, and medication discrepancies have been reported as accounting for over half of the medication errors.³⁴ Numerous studies have shown that medication errors impact unplanned use of health care.^{35 36 37} For example, Coleman et al.³⁸ reported that patients with medication discrepancies have significantly higher rate of readmission compared to those without such discrepancies.

As the population of people over 65 years continues to increase, the absolute number of people with psychosis will also grow. The frequency of older adults with psychosis occupying nursing home beds will likely increase faster than those patients in the general population. This means that the percentage of patients appropriately and successfully managed with antipsychotic medications will rise. The current quality metric indicates with the percentage that “lower is better.” This confuses the public and creates situations where it may appear that a skilled nursing facility is providing worse care even if the facility is appropriately administering an antipsychotic agent to a patient.

For this reason, our organizations strongly urge CMS to reconsider current limitations on antipsychotic use to treat NPS. **CMS should consider removal of the requirement to count residents in skilled nursing facilities who are prescribed antipsychotics for FDA-approved indications used appropriately, as defined by FDA indication or evidence-based research, from both of the following quality metrics:**

- 1) Percentage of short-stay residents who got antipsychotic medication for the first time, and
- 2) Percentage of long-stay residents who got an antipsychotic medication as an as-needed (PRN) medication or standing medication when used for FDA approved indications.

We refer CMS to a thorough discussion of appropriate alternative measure specifications aligned to FDA approved indications and CMS guidelines found in the *International Journal of Geriatric Psychiatry*, “Antipsychotic Medication Use in Nursing Homes: A Proposed Measure of Quality.”³⁹

New ICD-10 Codes for Dementia-Related Psychosis are Needed to Better Ensure the Appropriate Care for Affected Patients

The impact of dementia is great, regardless of setting, in terms of emotional, financial, and physical demands for both patients and their caregivers. Evidence suggest that patients with neuropsychiatric symptoms of dementia experience worse outcomes. Behavioral and psychological symptoms of dementia are recognized as common manifestations of dementia and may include agitation, aggression, and psychosis. Although these symptoms can occur in tandem with each other, each symptom can occur individually and warrants specific interventions. Current ICD-10 diagnostic codes do not specifically differentiate dementia-related psychosis. Symptoms of dementia-related psychosis include delusions (false beliefs) and hallucinations (seeing or hearing things that others do not see or hear). This gap is negatively affecting outcomes for patients whose health care providers fail to appropriately identify, document, and/or address such symptoms in their care plans.

³⁴ Rozich JD, Howard RJ, Justeson JM et al. Standardization as a mechanism to improve safety in health care. *Jt Comm J Qual Saf*, 2004; 30: 5–14.

³⁵ Dedhia P, Kravet S, Bulger J et al. A quality improvement intervention to facilitate the transition of older adults from three hospitals back to their homes. *J Am Geriatr Soc*, 2009; 57: 1540–1546.

³⁶ Schnipper JL, Hamann C, Ndumele CD et al. Effect of an electronic medication reconciliation application and process redesign on potential adverse drug events: a cluster-randomized trial. *Arch Intern Med*, 2009; 169: 771–780.

³⁷ Jack BW, Chetty VK, Anthony D et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med*, 2009; 150: 178–187.

³⁸ Coleman EA, Smith JD, Raha D et al. Posthospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med*, 2005; 165: 1842–1847.

³⁹ Lucas, J. A., et al (2014), Antipsychotic medication use in nursing homes: a proposed measure of quality, *International Journal of Geriatric Psychiatry*, 29, pages 1049–1061.

To evaluate opportunities for addressing this gap, The Gerontological Society of America convened a multidisciplinary group of stakeholders for a roundtable discussion in Washington, DC, on April 25, 2019. The objective of this discussion was to assess the possible need for and value of a new ICD-10 code for dementia-related psychosis to ensure that patients with dementia receive appropriate care.

Because there is no code specific to dementia-related psychosis, many providers do not record the presence of this condition in patients' medical records. As an alternative, providers sometimes use a code for "behavioral disturbance" for patients who present with delusions and/or hallucinations. The ICD-10 codes for behavioral disturbance are defined as behaviors that are aggressive, combative, or violent, which is not reflective of psychosis. Clinicians, allied health professionals, and patient advocates are concerned about whether the behavioral disturbance code is appropriate for dementia-related psychosis. Behavioral disturbance is defined as violent, aggressive, or combative behavior—which is not reflective of psychosis. This code does not encourage providers to implement interventions that are appropriate for managing delusions and hallucinations or other clinical needs⁴⁰ Moreover, some long-term care facilities may refuse to admit patients who have this code in their files.²

A recent study conducted by The Moran Company examined coding for dementia-related conditions in 2016–2017 Medicare claims data.⁴¹ The objectives of this study were to assess how health care providers code for dementia-related conditions in various settings and to identify patterns of coding. The study assessed the proportion of beneficiaries who initially received a dementia diagnosis and later also received either a diagnosis of psychosis, behavioral disturbance, or both. It also examined whether beneficiaries received "G" codes for underlying diseases or "F" codes, which are dementia diagnosis codes. This study found that most beneficiaries with dementia received a code only for a dementia diagnosis with no additional diagnosis for psychosis. This finding was consistent for all dementia subtypes. Among patients who received an additional diagnosis code, most were coded as having a behavioral disturbance rather than psychosis.

Dementia-related psychosis is a highly prevalent condition that often manifests in patients with dementia but is underdiagnosed. Better diagnostic clarity will drive more careful attention to dementia-related psychosis. It follows that the development of ICD-10 codes specific to dementia-related psychosis could improve documentation of the condition and subsequent care planning activities. **The field could benefit from further research on evidence-based strategies for treating dementia-related psychosis.**

Recommendations

A summary list of our recommendations include:

1. Expand CMS recognition of FDA approved uses for psychotropic and antipsychotic medications for the treatment of neuropsychiatric disorders in late-life;
2. CMS to establish a mechanism for inclusion of new medications receiving FDA indications for treatment of NPS;
3. CMS to remove the requirement to count residents in skilled nursing facilities who are prescribed antipsychotics for FDA-approved indications used appropriately, as defined by FDA indication or evidence-based research, from quality metrics for both short and long term stay residents receiving standing or as-needed antipsychotics medication for FDA-approved indications;
4. CMS integration of diagnostic criteria and clinical guidelines into nursing home operator, medical director, nursing, and surveyor trainings; and

⁴⁰ Gerontological Society of America. *ICD-10 Codes for Documenting Dementia-Related Psychosis: An Expert Roundtable Summary*. Washington, DC; April 25, 2019.

⁴¹ Moran Company. Dementia Diagnosis Landscape: Diagnoses Following an Initial Dementia Diagnosis in the Medicare Population. Presented at: The Gerontological Society of America Roundtable Discussion on the Potential Modification to ICD-10 Codes; April 25, 2019; Washington, DC.

5. CMS sponsorship of population health studies which result in evidence-based clinical guidelines guiding the use of psychotropic and antipsychotic medications for the treatment of neuropsychiatric disorders in late-life.

Conclusion

There are no disease-modifying treatments for dementia; therefore, clinicians focus on decreasing patients' suffering and improving their quality of life. Nearly all patients with dementia will develop at least one NPS. The underlying cause of these behaviors may be neurobiological, an acute medical condition, unmet needs or a pre-existing psychiatric illness. Because of this complexity, treatment should begin with an assessment to rule out potentially reversible causes of NPS. For mild to moderate NPS, short-term behavioral interventions, followed by pharmacologic interventions, are used. For moderate to severe NPS, pharmacologic interventions and behavioral interventions are often used simultaneously. New ICD-10 codes for dementia-related psychosis would likely help prescribers with more accurate diagnosis and clearer guardrails for appropriate use. Assessing triggers and selecting strategies, however, is time-intensive and reflects a paradigm shift necessitating a reorganization of dementia care.

Thank you for considering our comments. Please contact Sue Peschin at 202-688-1246 or speschin@agingresearch.org with questions or additional information. We are open and ready to help develop training and policy solutions together. Millions of beneficiaries stand to benefit and there's no time like the present.

Sincerely,

Alliance for Aging Research
AMDA - The Society for Post-Acute and Long-Term Care Medicine
American Association of Geriatric Psychiatry
American Society of Consultant Pharmacists (ASCP)
Caregiver Action Network and Caregiver Voices United
TEAMHealth
The Gerontological Society of America