March 13, 2020
Chairman Toomey
Ranking Member Stabenow
Senate Committee on Finance
Subcommittee on Health Care
219 Dirksen Senate Office Building
Washington, DC 20510-6200

Re: Subcommittee on Health Care Seeks Feedback on Actions to Address Alzheimer's Disease

Chairman Toomey and Ranking Member Stabenow:

Project PAUSE (Psychoactive Appropriate Use for Safety and Effectiveness) is a coalition of patient advocacy and provider organizations concerned with the safety and effectiveness of antipsychotic medication utilization in America's nursing homes. Our leadership is comprised of nonprofit medical associations, patient protection groups, policymakers, and geriatric thought-leaders.

We are grateful for the opportunity to comment on the Senate Finance Subcommittee on Health Care's request for feedback on actions to address Alzheimer's disease. We have limited our comments to specific sections of the changes aimed at protecting vulnerable patients and encouraging innovation, which directly impact the senior beneficiaries we aim to protect.

Background
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. Evidence suggests that persons with dementia with NPS experience worse outcomes than those without NPS, including greater impairment in activities of daily living, worse quality of life, shorter time to severe dementia and accelerated mortality.[i] Effectively managing or preventing NPS that cause distress and potential harm to self and others is a key part of person-centered care and crucial to the wellbeing of residents and family caregivers. However, residents in long-term care facilities who have dementia-related psychosis or other conditions that could benefit from antipsychotic medication (e.g., bipolar depression) may face barriers to accessing appropriate pharmacotherapy. Discontinuing antipsychotic medication upon admission to a long-term care facility can precipitate a further decline in function and behavior and set the resident on a trajectory of decline.[ii]

To address this challenge, The Centers for Medicare & Medicaid Services (CMS) document and report antipsychotic utilization rates in long-term care settings throughout the country. In March 2012, CMS launched a quality initiative with the goal of decreasing use of antipsychotics in nursing homes by 15% by the end of 2012.[1] This initiative established the current antipsychotic utilization rate quality measure and created *The National Partnership to Improve Dementia Care* (the Partnership). The Partnership's official measure to determine antipsychotic utilization rates is the percentage of long-stay nursing home residents who are receiving an antipsychotic medication, excluding those residents diagnosed with schizophrenia, Huntington's Disease, or Tourette's Syndrome and the percentage of short stay nursing home residents who are initiated on an antipsychotic after admission to the skilled nursing facility. The

[i] Karttunen K, Karppi P, Hiltunen A, et al. Neuropsychiatric symptoms and quality of life in patients with very mild and mild Alzheimer's disease. Int J Geriatric Psychiatry. 2011;26(5):473–482.Karttunen K, Karppi P, Hiltunen A, et al. Neuropsychiatric symptoms and quality of life in patients with very mild and mild Alzheimer's disease. Int J Geriatric Psychiatry. 2011;26(5):473–482.
[2]Gerontological Society of America. ICD-10 Codes for Documenting Dementia-Related Psychosis: An Expert Roundtable Summary. Washington, DC; April 25, 2019.
[1] CMS Newsroom; available at: https://www.cms.gov/newsroom/fact-sheets/data-show-national-partnership-improve-dementia-care-achieves-goals-reduce-unnecessary-antipsychotic

Partnership adopted these three excluded conditions as they have been recognized under CMS regulations since 2006,[2] but it is important to note that these conditions are not the only U.S. Food and Drug Administration (FDA) approved indications for antipsychotic medication use.[3] Project PAUSE has complied a full list of FDA-approved adult indications for first-generation antipsychotics and second-generation antipsychotics (*see appendix*)[4].

In an effort to ensure that elderly patients have access to critical medications and that we continue to encourage groundbreaking new therapies to address symptoms associated with Alzheimer's Dementia, we urge the subcommittee to request the following improvements to CMS' quality measure:

- Expand CMS recognition of FDA approved uses for psychotropic and antipsychotic medications for the treatment of neuropsychiatric disorders in late-life;

- Update the current measure to meet the *Program-Specific Measure Needs and Priorities* set forth by CMS' Center for Clinical Standards and Quality (CCSQ);[5]

- Improve CMS integration of diagnostic criteria and clinical guidelines into nursing home operator, medical director, nursing, and surveyor trainings;

- Take advantage of the interdisciplinary use of the Long-Term Care Facility Resident Assessment Instrument (RAI) User's Manual; and

- Further promote quality excellence through incorporating advanced practice practitioners (APPs) and consultant pharmacist's review of antipsychotic medications in the documentation of antipsychotic use in the RAI User's Manual

We have attached Project PAUSE's formal recommendations for encouraging new therapies and protecting patient access to needed Alzheimer's medication therapies.

Thank you for the opportunity to help improve patient care for patients with Alzheimer's Dementia. If you have any questions or require additional information, please contact Veronica Charles at vcharles@ascp.com. We look forward to working with the Subcommittee to reduce inappropriate antipsychotic utilization rates and improve patient access and encourage new therapies

Sincerely,

Project PAUSE

[2] The Quality of Antipsychotic Drug Prescribing in Nursing Homes; available at: https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/486595
[3] FDA Drug Databases: FDA Approved Drugs; available at: https://www.accessdata.fda.gov/scripts/cder/daf/
[4] Agency for Healthcare Research and Quality (US); Feb 2012: *Future Research Needs for First- and Second-Generation Antipsychotics for Children and Young Adults* No. 13, Appendix A: Table A1 and A2; available at: https://www.ncbi.nlm.nih.gov/sites/books/NBK84660/
[5]CCSQ Program-Specific Measure Needs and Priorities; available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/2019-CMS-Measurement-Priorities-and-Needs.pdf

Executive Summary

The Centers for Medicare and Medicaid Services (CMS) document and report antipsychotic utilization rates in long-term care settings throughout the country. In March 2012, CMS launched a quality initiative with the goal of decreasing use of antipsychotics in nursing homes by 15% by the end of 2012.[3] This initiative established the current antipsychotic utilization rate quality measure and created *The National Partnership to Improve Dementia Care* (the Partnership).

The Partnership's official measure to determine antipsychotic utilization rates is the percentage of long-stay nursing home residents who are receiving an antipsychotic medication, excluding those residents diagnosed with schizophrenia, Huntington's Disease, or Tourette's Syndrome and the percentage of short stay nursing home residents who are initiated on an antipsychotic after admission to the skilled nursing facility (*see figure 1*). The Partnership adopted these three excluded conditions as they have been recognized under CMS regulations since 2006,[4] but it is important to note that these conditions are not the only U.S. Food and Drug Administration (FDA) approved indications for antipsychotic medication use.[5] PAUSE has complied a full list of FDA-approved adult indications for first-generation antipsychotics (*see figure 2*) and second-generation antipsychotics (*see figure 3*)[6].

The current measure utilized to determine CMS antipsychotic quality measures uses the medication list from the MDS, discounting any residents with schizophrenia, Huntington's chorea, and/or Tourette's syndrome. This current measure does not take advantage of the interdisciplinary use of the Long-Term Care Facility Resident Assessment Instrument (RAI) User's Manual (*see figure 4*). The RAI is used by nursing homes and long-term care facilities (LTCFs) to gather information on a resident's clinical needs and it allows care teams to create individualized care plans for patients. This care plan is the product of best clinical practices and clinical intervention and helps create a holistic approach to patient care that allows residents to maintain their highest quality of life.[7] This RAI resource utilizes clinical rationale to determine whether or not a patient requires a gradual dose reduction (GDR) of an antipsychotic medication or whether or not an antipsychotic mediation is clinically contraindicated. In order for CMS to enforce best clinical practices and ensure appropriate antipsychotic utilization in nursing homes and LTCFs, the agency should incorporate a meaningful antipsychotic utilization measure using these inputs outlined in CMS' RAI manual. To assist the Partnership and CMS in enforcing the antipsychotic utilization measures outlined in the RAI, PAUSE proposes that the agency update the quality measure to reflect only those residents using inappropriate antipsychotic drugs as determined by their prescriber and consultant pharmacist and verified on the RAI.

[3] CMS Newsroom; available at: https://www.cms.gov/newsroom/fact-sheets/data-show-national-partnership-improve-dementia-care-achieves-goals-reduce-unnecessary-antipsychotic

[4] The Quality of Antipsychotic Drug Prescribing in Nursing Homes; available at: https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/486595

[5] FDA Drug Databases: FDA Approved Drugs; available at: https://www.accessdata.fda.gov/scripts/cder/daf/

[6] Agency for Healthcare Research and Quality (US); Feb 2012: *Future Research Needs for First- and Second-Generation Antipsychotics for Children and Young Adults* No. 13, Appendix A: Table A1 and A2; available at: https://www.ncbi.nlm.nih.gov/sites/books/NBK84660/

Quality Measure Improvement

CMS' current quality measure impacts clinical practice in unintended ways. Attempts to comply with reductions in the measure can lead to skilled nursing facilities denying admission and can lead to the use of medications that are outside of the antipsychotic class and go against best clinical evidence. By updating the antipsychotic utilization quality percentage to incorporate a new three-pronged documentation approach, the antipsychotic utilization quality domain will be based on evidence, treatment guidelines, and FDA-approved indications for use and will be consistent with already existing CMS Interpretive Guidelines.

The current measure fails to meet the *Program-Specific Measure Needs and Priorities* set forth by CMS' Center for Clinical Standards and Quality (CCSQ).[8] The measure also does not adjust for clinical rationale and it inadvertently disadvantages facilities based on size, location, and/or clinical specialty.

> *Criterium a: Measure **does not** support the Meaningful Measure Initiative by addressing a Meaningful Measure area and prioritizing outcomes measures, patient reported outcome measures (PROMs), and electronic measures when possible.*

The current measure reports the percentage of long-stay residents who are receiving antipsychotic drugs in the target period. These reported figures represent the current count of patients receiving a certain drug class of treatment and do not account for appropriateness as defined by patient health outcomes and/or thoughtful clinical rationale. We propose building upon the antipsychotic measures collected in the RAI to better prioritize meaningful outcomes.

> *Criterium c: Measure **does not** have a strong scientific evidence base to demonstrate that the measure when implemented can lead to the desired outcomes and/or more affordable care (i.e., NQF's Importance criteria).*

The current measure lacks scientific evidence and the reported figures do not correlate with appropriate antipsychotic utilization rates in nursing homes and LTCFs. The RAI measures that PAUSE supports are specific to antipsychotics and do incorporate many clinically proven tools (like gradual dose reductions [GDRs]) and includes review from a resident's care team.

> *Criterium g: Measure results and performance **do not** identify opportunities for improvement.*

The current measure is limited in scope. The basic reporting of the number of residents taking antipsychotic medication(s) does not provide any information on the number of residents whose conditions indicate antipsychotic medication(s), nor does it provide an opportunity for a patient's care team to articulate proper/improper utilization of medications. In an effort to reduce the amount of inappropriate antipsychotic utilization rates in nursing homes and LTCFs and identify room for care improvement, more robust information is needed. The RAI includes better patient assessment information to properly meet this criteria.

> *Criterium h: The use of this measure in a program **does** result in negative unintended consequences (**denial of treatment, limiting access to care, creating provider burden**).*

[8]CCSQ Program-Specific Measure Needs and Priorities; available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/2019-CMS-Measurement-Priorities-and-Needs.pdf

The current measure has created a multitude of negative unintended consequences. As PAUSE continues to work with CMS to reduce inappropriate use of antipsychotic utilization rates, the medical community has become increasingly aware of the negative impact that the current limited metric has on denying antipsychotic medications to patients with a necessary, FDA-approved indication.

The current measure also creates unnecessary burden on patients, facilities, and providers, as patient care teams are documenting more meaningful information pertaining to antipsychotic utilization in the RAI but are still subject to the reports of the nonclinical figures that CMS requires. The measure currently utilized by the Partnership also does not adjust for clinical rationale and it inadvertently disadvantages facilities based on size, location, and/or clinical specialty.

Disadvantages Based on Facility Size

As the population of people over 65 years old continues to increase, the absolute number of patients suffering from psychosis will continue to grow.[9] The current quality measure utilized by The Partnership indicates that "lower is better" which fails to adjust for the increasing patient population and the additional services that these patients will require as they continue to age beyond that of the current population.[10] The current measure will only continue to create situations where it may appear that a skilled nursing facility is providing worsening care, when in fact they are adapting to the needs of an aging population.

Since the current measure used to determine antipsychotic utilization is calculated using a percentage of total antipsychotic utilization for long-stay residents, some nursing homes may have five patients suffering from Bipolar disorder and five patients with major depressive disorder in their 50 bed facility but would appear to have an abnormally high rate of antipsychotic medication use. This is because the quality measure is based on a percentage. If a large facility had double the number of residents utilizing antipsychotic medications, their quality measure would not solicit any concern from CMS, even though they have more individuals currently utilizing antipsychotic medications. This systemic problem disproportionately impacts patients and facilities in rural communities.

Disadvantages Based on Facility Location

Utilizing a generic percentage as a quality metric does not properly capture the size and scope of the problem, which is evident in many rural facilities across the country.[11] Rural facilities are more likely to house a smaller number of residents, which means that any resident receiving antipsychotic medications, appropriate or inappropriate, has the potential to negatively impact a rural facility. This can lead to denial of care for the frailest patients living in rural communities.[12] In order to prevent undue burden on rural facilities, CMS needs to utilize more robust data to properly articulate the rate of inappropriate antipsychotic utilization rates.

Disadvantages Based on Clinical Expertise

Many nursing homes and LTCFs are beginning to specialize in treating residents with complex conditions[13]. A facility may choose to take in more patients with moderate dementia and psychotic symptoms due to management expertise. This facility may have a large percentage of patients

[9] Folsom, David P et al. "Schizophrenia in late life: emerging issues." *Dialogues in clinical neuroscience* vol. 8,1 (2006): 45-52.
[10] Knickman, James R, and Emily K Snell. "The 2030 problem: caring for aging baby boomers." *Health services research* vol. 37,4 (2002): 849-84. doi:10.1034/j.1600-0560.2002.56.x
[11] Assessing the Unintended Consequences of Health Policy on Rural Populations and Places; available at: http://www.rupri.org/wp-content/uploads/Evaluating-the-Impact-of-Policy-Changes-on-Rural-Populations-1.pdf
[12] Bowblis, John R et al. "The urban-rural disparity in nursing home quality indicators: the case of facility-acquired contractures." *Health services research* vol. 48,1 (2013): 47-69. doi:10.1111/j.1475-6773.2012.01431.x
[13] The Top Trends in Home Care for 2019; available at: https://homehealthcarenews.com/2019/01/the-top-trends-in-home-care-for-2019%EF%BB%BF/

appropriately treated with antipsychotics and, again, be disadvantaged by the use of the current quality measure since CMS looks at the total number of patients taking antipsychotic medications rather than the amount of inappropriate use. This has the unintended consequence of deemphasizing excellence in dementia and psychotic symptom care.

Alternative Quality Measure(s)

As represented through CMS' RAI User Manual, there are current federal and clinical standards in place to help mitigate inappropriate antipsychotic usage. Medication management is a clinical tool centered around the unique pharmacologic expertise of a consultant pharmacist and a patient's primary health care provider to tailor a patient's medication usage to their individual needs.[14] Medication management standards are published in the State Operations Manual (SOM), which provides each individual state and CMS with regulatory oversight and authority.[15] PAUSE urges CMS to incorporate uniform language when measuring antipsychotic utilization rates and change the Partnership's antipsychotic measure to include antipsychotic utilization as determined through the RAI User Manual (see figure 4). We also urge CMS to further promote quality excellence through incorporating consultant pharmacist's review of antipsychotic medications in the documentation of antipsychotic use.

N0450. Antipsychotic Medication Review	
Enter Code ☐	**A. Did the resident receive antipsychotic medications since admission/entry or reentry to the prior OBRA assessment, whichever is more recent?** 0. **No** – Antipsychotics were not received → Skip N0450B, N0450C, N0450D, and N0450E 1. **Yes** – Antipsychotics were received on a routine basis only → Continue to N0450B, Has a GDR been attempted? 2. **Yes** – Antipsychotics were received on a PRN basis only → Continue to N0450B, Has a GDR been attempted? 3. **Yes** – Antipsychotics were received on a routine and PRN basis → Continue to N0450B, Has a GDR been attempted?
Enter Code ☐	**B. Has a gradual dose reduction (GDR) been attempted?** 0. **No** → Skip to N0450D, documented GDR as clinically contraindicated *or documented use of the drug and dose as clinically appropriate* 1. **Yes** → Continue to N0450C, Date of last attempted GDR
	C. Date of last attempted GDR: ☐☐ - ☐☐ - ☐☐☐☐ Month Day Year
Enter Code ☐	**D. Documented GDR as clinically contraindicated or documented use of the drug and dose as clinically appropriate** 0. **No** – GDR has not been documented by *BOTH physician and pharmacist* as clinically contraindicated *or documented use of the drug and dose as clinically appropriate* → Skip N0450E Date *physician or pharmacist* documented GDR as clinically contraindicated *or documented use of the drug and dose as clinically appropriate* 1. **Yes** – GDR has been documented *by BOTH physician and pharmacist* as clinically contraindicated *or documented use of the drug and dose as clinically appropriate* → Continue to N0450E, Effective date of documented GDR as clinically contraindicated *or documented use of the drug and dose as clinically appropriate*
	E. Date of documented GDR as clinically contraindicated *or documented use of the drug and dose as clinically appropriate:* ☐☐ - ☐☐ - ☐☐☐☐ Month Day Year

In the above example, accurate documentation of medication management and medication regimen review would be incorporated into the quality measure. PAUSE firmly asserts that this process is the best multifaceted approach to empower CMS and other authorities with the information needed to determine if antipsychotic utilization is inappropriate without threatening patient access to medically necessary medications.

[14] American Society of Consultant Pharmacists. Consultant Pharmacist Handbook: A Guide for Consulting to Nursing Facilities. Fifth Edition. 2018;4:33-57.
[15] CMS State Operations Manual; available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

This new documentation would create a representative percentage of antipsychotic utilization through utilizing:

D. (0) *GDR has not been documented by the advanced practice practitioner and pharmacist as clinically contraindicated or documented the use and dose as clinically appropriate +*

The total number of long stay residents who are in a nursing home for greater than 100 days during the reporting interval[16]

A [SUM D. (0)]
B [SUM of long stay residents who are in the nursing home for greater than 100 days during the reporting interval]

This new percentage will more closely reflect potential inappropriate antipsychotic usage in nursing homes.

Under this proposed measure, advanced practice practitioners (APPs) would continue to document their clinical rationale for prescribing an antipsychotic medication and the facility's consultant pharmacist would continue to document gradual dose reduction (GDR) and medication regimen review (MRR) information. The Minimum Data Set (MDS) coordination would document that the APP and the consultant pharmacist performed their required reviews. These checks and balances will enforce patient centered care and quality data surrounding the use of antipsychotics. Any concern regarding an unnecessary use of a medication would still be investigated and reported by the surveyor, which is current practice. Should a state surveyor not find the three-pronged documentation certifying antipsychotic utilization in a facility, the facility would be considered to be inappropriately prescribing antipsychotic medications. The new metric would reflect the percentage of residents that are potentially inappropriately treated with an antipsychotic.
Further addressing documentation as part of the antipsychotic use measure will also address other shortcomings of the current quality measure that do not allow CMS to collect all information pertaining to antipsychotic utilization in nursing homes. It will also allow for patient care to adapt to new evidence and new and future FDA approvals that have antipsychotic compounds to treat behaviors and psychosis that are in late phases of development.

Patients and health care practitioners can be limited in taking advantage of new evidence or of advancements in treatments under the current quality metric. This forces health care practitioners to decide between what is best for patients and what best addresses the current CMS quality measures.

Thank you for the opportunity to help improve patient care in America's nursing homes. If you have any questions or require additional information, please contact our office. We look forward to working with CMS to reduce inappropriate antipsychotic utilization rates and improve patient access and quality of care.

[16] Design for Nursing Home Compare Five-Star Quality Rating System: Technical Users' Guide October 2019; available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/downloads/usersguide.pdf

PAUSE

Appendix 1

Figure 1

Percent of residents who received an antipsychotic medication	This measure reports the percentage of long-stay residents who are receiving antipsychotic drugs in the target period. Reducing the rate of antipsychotic medication use has been the focus of several CMS initiatives.

Figure 2

Tables of FDA-Approved Indications for First-Generation Antipsychotics[17]

Generic Name	Indications	Age Group for Which Approved
Chlorpromazine	Schizophrenia	Adults and children (1–12 years)
	Bipolar disorder (mania)	
	Severe behavioral problems	
Droperidol	Agitation	Adults and children
Fluphenazine	Psychotic disorders	Adults
Haloperidol	Schizophrenia	Adults
	Tourette syndrome	
	Hyperactivity	
	Severe childhood behavioral problems	
Loxapine	Schizophrenia	Adults and children ≥12 years
Perphenazine	Schizophrenia	Adults and children ≥12 years
Pimozide	Tourette syndrome	Adults and children ≥12 years
Prochlorperazine	Schizophrenia	Adults and children >2 years and >20 pounds
	Generalized nonpsychotic anxiety	Adults
Thiothixene	Schizophrenia	Adults and children ≥12 years
Thioridazine	Schizophrenia	Adults and children
Trifluoperazine	Schizophrenia	Adults and children ≥6 years
	Generalized nonpsychotic anxiety	Adults
Promethazine	Perennial and seasonal allergic rhinitis.	Adults and children
	Vasomotor rhinitis.	
	Allergic conjunctivitis due to inhalant allergens and foods.	
	Mild, uncomplicated allergic skin manifestations of urticaria and angioedema. Amelioration of allergic reactions to blood or plasma.	
	Dermographism.	

17 FDA approved indications; updated 03/22/2018

	Anaphylactic reactions, as adjunctive therapy to epinephrine and other standard measures, after the acute manifestations have been controlled.	
	Preoperative, postoperative, or obstetric sedation.	
	Prevention and control of nausea and vomiting associated with certain types of anesthesia and surgery.	
	Therapy adjunctive to meperidine or other analgesics for control of post-operative pain.	
	Active and prophylactic treatment of motion sickness.	
	Sedation in both children and adults, as well as relief of apprehension and production of light sleep from which the patient can be easily aroused.	
	Antiemetic therapy in postoperative patients.	

Figure 3

Tables of FDA-Approved Indications for Second-Generation Antipsychotics[18]

Generic Name	Indications	Age Group for Which Approved
Aripiprazole	Schizophrenia	Adults and adolescents (13–17 years)
	Bipolar disorder (manic/mixed) monotherapy or adjunctive to lithium or valproate	Adults and children (10–17 years)
	Adjunctive treatment of major depressive disorder	Adults
	Irritability Associated with autistic disorder	Children (6–17 years)
	Acute treatment of agitation	Adults
Asenapine	Acute schizophrenia	Adults
	Bipolar disorder type 1 (manic/mixed)	
Clozapine	Treatment resistant schizophrenia	Adults
	Reduce the risk of suicidal behavior in younger patients with schizophrenia.	
Iloperidone	Acute schizophrenia	Adults
Olanzapine	Schizophrenia Bipolar disorder (manic/mixed)	Adults and adolescents (13–17 years)
	Bipolar disorder	Adults
	Treatment resistant depression	
	Agitation associated with schizophrenia and bipolar I mania	

18 FDA approved indications; updated 03/22/2018.

Paliperidone	Schizophrenia Schizoaffective disorder	Adults
Quetiapine	Schizophrenia	Adults and adolescents (13–17 years)
	Bipolar disorder (acute manic)	Adults, children, and adolescents (10–17 years)
	Bipolar disorder (depression)	Adults
	Bipolar disorder (maintenance)	
	Adjunctive therapy for major depressive disorder	
Risperidone	Schizophrenia	Adults and adolescents (13–17 years)
	Bipolar disorder (manic/mixed)	Adults and adolescents (10–17 years)
	Irritability associated with autism	Children (5–16 years)
Ziprasidone	Schizophrenia	Adults
	Bipolar disorder (manic/mixed)	
	Bipolar disorder (maintenance)	
	Acute agitation in patients with schizophrenia	
Pimavancerin	Treatment of Hallucinations and Delusions associated with Parkinson's Disease Psychosis	Adults
Brexpiprazole	Schizophrenia	Adults
	Adjunctive treatment of major depressive disorder	
Lumateperone	Schizophrenia	Adults
Cariprazine	Treat Bipolar depression and the short term treatment of manic or mixed episodes that happen with bipolar 1 disorder	Adults
Lurasidone	Treatment of major depressive episode associated with bipolar I disorder (bipolar depression)	Adults and children (10 to 17 years)
	Adjunctive treatment with lithium or valproate with bipolar depression.	Adults

FDA approved indications; updated 03/22/2018

Figure 4

N0450. Antipsychotic Medication Review	
Enter Code ☐	**A. Did the resident receive antipsychotic medications since admission/entry or reentry to the prior OBRA assessment, whichever is more recent?** 0. **No** – Antipsychotics were not received → Skip N0450B, N0450C, N0450D, and N0450E 1. **Yes** – Antipsychotics were received on a routine basis only → Continue to N0450B, Has a GDR been attempted? 2. **Yes** – Antipsychotics were received on a PRN basis only → Continue to N0450B, Has a GDR been attempted? 3. **Yes** – Antipsychotics were received on a routine and PRN basis → Continue to N0450B, Has a GDR been attempted?
Enter Code ☐	**B. Has a gradual dose reduction (GDR) been attempted?** 0. **No** → Skip to N0450D, Physician documented GDR as clinically contraindicated 1. **Yes** → Continue to N0450C, Date of last attempted GDR
	C. Date of last attempted GDR: ☐☐ - ☐☐ - ☐☐☐☐ Month Day Year
Enter Code ☐	**D. Physician documented GDR as clinically contraindicated** 0. **No** – GDR has not been documented by a physician as clinically contraindicated → Skip N0450E Date physician documented GDR as clinically contraindicated 1. **Yes** – GDR has been documented by a physician as clinically contraindicated → Continue to N0450E, Date physician documented GDR as clinically contraindicated
	E. Date physician documented GDR as clinically contraindicated: ☐☐ - ☐☐ - ☐☐☐☐ Month Day Year