



November 15, 2021

The Honorable Ron Wyden
Chairman
U.S. Senate Committee on Finance
219 Dirksen Senate Office Building
Washington D.C. 20510-6200

The Honorable Mike Crapo
Ranking Member
U.S. Senate Committee on Finance
219 Dirksen Senate Office Building
Washington D.C. 20510-6200

Re: Request for Information (RFI) on Proposals to Address Unmet Mental Health Needs

Dear Chairman Wyden and Ranking Member Crapo:

[Project PAUSE \(Psychoactive Appropriate Use for Safety and Effectiveness\)](#) represents an ad hoc coalition of national patient and professional organizations that collectively advocates on clinical care regulatory and legislative issues in long-term care (LTC) and the community with a focus on improving the quality of life and care for individuals living with neurodegenerative diseases, such as dementia. Project PAUSE has been engaging with the Centers for Medicare & Medicaid Services (CMS) to promote policies in LTC settings that curb the inappropriate use of antipsychotics, and psychotropics overall, and ensure access and appropriate use of these medications by residents who may clinically benefit and for whom non-pharmacologic interventions alone are no longer effective.

The coalition appreciates the opportunity to submit information to the Committee regarding unmet mental health needs, especially for individuals insured by Medicare, Medicaid, Children's Health Insurance Program (CHIP) or Affordable Care Act (ACA) marketplace plans. Our comments address the following:

- Protecting Access to Critical Medicines,
- Access to Long-Term Care for Individuals with Mental Health Challenges
- Determining Appropriate Use of Antipsychotics, and
- Long-Term Care Workforce Mental Health.

We greatly appreciate your time and attention to these comments; feel free to reach out with any questions related to this information.

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PROTECTING ACCESS TO CRITICAL MEDICINES

When CMS released the Medicare Prescription Drug Benefit Manual in 2005, the agency developed a policy affecting drug classes that it entitled “Classes of Clinical Concern.” Under the policy, a Part D plan is required to cover all or substantially all drugs in the following six therapeutic classes: anti-retrovirals; immunosuppressants when used for organ rejection; anti-depressants; anti-psychotics; anti-convulsant agents; and anti-neoplastics. Moreover, Part D plans may not impose step therapy or prior authorization requirements for these drugs for beneficiaries who are currently taking the drug: both beneficiaries who are currently enrolled in the plan, as well as beneficiaries taking a protected class drug that are newly enrolled in the plan.¹ In July 2008, Congress passed the Medicare Improvements for Patients and Providers Act (MIPPA) into law. MIPPA amended section 1860D-4 of the Social Security Act (detailing beneficiary protections for Part D enrollees), authorizing CMS to establish a new regulatory review process for the purpose of identifying those drug classes for which a Part D plan would be required to include all drugs on its formulary. In particular, the MIPPA language directed the Secretary to identify those categories and classes of drugs which meet two criteria: (1) where restrictions on that class would have major or life-threatening consequences; and (2) where there is a significant need for individuals which a disease or disorder treated by the drugs in the class to have access to multiple drugs within that class. Notably, the MIPPA language did not reference the existing six protected classes.

Despite strong support from Congress and patients to maintain access to these medicine classes, CMS through the Center for Medicare & Medicaid Innovation (CMMI) has proposed opportunities, including through demonstration studies, for plans to make changes that could restrict access to these critical and effective medicines. Preserving these “Six Protected Classes” is critical to ensuring that individuals properly managed on specific medicines have access to the most appropriate, useful, and beneficial medicine for them and their situation. **To ensure that access to medicines within the six protected classes, we recommend legislative efforts that protect the six protected classes in statute.**

While ensuring access to needed medicines via insurance plans is critical to supporting individuals well-managed on antipsychotic medicines, CMS regulations aggressively restrict access to these medicines for long-term care residents via the “percentage of long-stay residents who got an antipsychotic medication” metric which impacts reimbursement and the Skilled Nursing Facilities (SNF) Five-Star Quality Program.

Psychogeriatric clinical guidelines recommend non-pharmacological approaches first for management of neuropsychiatric symptoms (NPS) in residents with dementia and other neurodegenerative diseases.² Dementia-associated NPS may include psychosis, wandering, sleep issues, agitation, depression, apathy and aggression; these symptoms can create challenges that disturb or harm the patient themselves and other residents. In

¹ Medicare Prescription Drug Benefit Manual (the “Manual”) Ch. 6 § 30.2.5, <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals>.

² <https://www.ipa-online.org/publications/guides-to-bpsd>.

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cases where residents living with dementia suffering from NPS present a threat to themselves or others, antipsychotic medications may be viewed as an option *if non-pharmacological treatments have been unsuccessful*.³ Clinical data shows that nearly all dementia patients will develop at least one NPS over the course of their disease and one-third of dementia patients will present with depression, an NPS, as their earliest observable symptom.⁴ NPS are associated with earlier death⁵; this fact supports the need for active treatment of these symptoms to prolong and improve quality of life.

Multiple

studies have illustrated the efficacy and safety of antipsychotic medicines in alleviating NPS, especially when an approach is well-targeted for patients. Importantly, the latest generation of antipsychotics and those currently in development are likely to have fewer incidences of adverse events, in comparison with previous treatments.⁶

Numerous health professional organizations have highlighted the need for appropriate use of antipsychotics, including in SNFs. CMS requires reporting on two antipsychotic quality measures, the percent of short stay residents who newly received an antipsychotic medication and the percent of long-stay residents who received an antipsychotic medication.⁷ Significantly, both quality measures impact the facility's 5-Star rating. The measure used in the SNF Five-Star Quality Program provides a basic calculation of the number of patients currently taking an antipsychotic divided by the facility's patient census. Our organizations have identified several areas of concern with the current measures:

- The measure exempts only three diagnoses from the calculation: Tourette's Syndrome, Huntington's Disease, and Schizophrenia. It fails to exempt use for conditions for which antipsychotics are well-established as providing clinical benefit, such as bipolar I disorder and major depressive disorder,
- According to CMS' Long-Term Care Facility Resident Assessment Instrument (RAI) 3.0 User's Manual, coding of medications is based on the medication's therapeutic category or pharmacological classification, not based on how it is used. So, if someone is receiving an antipsychotic for treatment of another medical condition, such as an antiemetic, its reason for use would not be captured.
- Only medications given during the "7-day look-back period" are coded. Therefore, if a resident receives a monthly injection of an antipsychotic, but that injection wasn't given in the 7-day look back of the MDS, it would not be coded.

³ 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>.

⁴ Masters MC, Morris JC, Roe CM. Noncognitive Symptoms of Early Alzheimer disease: A longitudinal analysis. *Neurology* 2015;84:617–622.

⁵ 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.

⁶ 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>.

⁷ https://downloads.cms.gov/files/mds-3.0-rai-manual-v1.17.1_october_2019.pdf

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More concerning, this measurement is not reflective of clinical best practice, nor does it provide accurate information on the quality or value of care provided to patients. Additionally, it also creates an incentive for the potentially inappropriate use of non-antipsychotic medications which are not clinically appropriate and have a higher risk of adverse events to manage neuropsychiatric symptoms (i.e., anti-epileptics), since these medications are not captured by the current metric. These incentives exist because the current measure reflects *any* use of antipsychotics, rather than identifying *inappropriate* use.

In 2012, the American Medical Association (AMA) established the Appropriate Use of Antipsychotic Medication in Nursing Homes policy (D-120.951) At the June 2019 AMA House of Delegates adopted amended resolution 708,⁸ which stated: “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.” A May 2021 Office of the Inspector General (OIG) report⁹ also plainly states, “These drugs can be effective in treating a range of conditions, but they carry risk and must be prescribed appropriately. Antipsychotic drugs are an important treatment for patients with certain mental health conditions.” The current CMS metric does not meet these standards and, in the mainstream opinion of healthcare providers, restricts access to medication that could benefit patients living with a chronic illness.

For patients who suffer from severe NPS, antipsychotic drugs used for FDA-approved indications can be used as part of a multidisciplinary care plan to successfully manage symptoms, both in and out of long-term care settings. The third section of this letter will outline a proposed measure that would enable increased oversight for antipsychotic use in long-term care facilities and verification that such medications are appropriate for a given patient and their needs.

ACCESS TO LONG-TERM CARE FOR INDIVIDUALS WITH MENTAL HEALTH CHALLENGES

In addition to restricting care access within long term care facilities, the current antipsychotic measure can also restrict access to facilities for individuals living with mental health issues and/or successfully utilizing antipsychotic medications as part of their current care plan in another care setting.

The nature of the measure creates perverse incentives for facility operators, leading to potential denial of admissions for those with pre-existing use of antipsychotic medications and refusal of re-admission or those placed on an antipsychotic during their hospitalization. These incentives exist due to the absence of measure sensitivity and failure to target inappropriate use of these medicines. The associated unintended consequences worsen patient outcomes, reduce appropriate management of mental health conditions, increase health inequities, and cause preventable patient harm.

⁸ [Appropriate Use of Antipsychotic Medications in Nursing Home Patients D-120.951](#)

⁹ [CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs, HHS OIG, May 2021](#)

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In practice, the CMS metric has served as a barrier to quality clinical care with negative financial ramifications for facilities that have higher absolute rates of use. Additionally, the current reporting mechanism for this measure also does not allow for variation between facilities, which can drive greater health inequities among communities of color and in rural regions. Many long-term care facilities specialize in caring for older adults with dementia, and many rural SNFs admit a higher percentage of residents with psychosis than urban facilities. Because of the case-mix of residents accepted, these facilities will likely have a higher percentage of residents utilizing antipsychotics, under the prescription and supervision of medical professionals. Such facilities are more likely to receive lower Five-Star scores *based solely on the composition of their patient population*.

In areas with limited long-term care options, this measure is actively restricting access to patients because of the successful treatments prescribed by their medical professional. The lack of direct relation to quality in the metric's score steers patients with dementia away from facilities most adept at providing appropriate treatment for their condition.

Data reported by CMS' National Dementia Partnership does not report on the percentage of nursing home residents with dementia by facility, so it is unclear whether anti-psychotic prescribing practices have truly decreased over time, or whether some facilities may be evicting some residents with challenging NPS or serious mental health issues or refusing to readmit them after hospitalization—this is a glaring data gap that should be explored.

While facilities cannot explicitly deny patients based on health status, many families report facing this reality. These scenarios exist for patients with a host of common, pre-existing mental health disorders including depression, anxiety, or post-traumatic stress disorder (PTSD). Conversely, a patient being effectively treated with an antipsychotic in a home or community-based setting might be forced to stop using a beneficial medicine if they need to enter a long-term care facility during their lifetime. Individuals with new or lifelong mental health disorders should not be denied access to long-term care because of their health conditions; however, poor measure design currently incentivizes patient denials.

DETERMINING APPROPRIATE USE OF ANTIPSYCHOTICS AND PSYCHOTROPICS

Project PAUSE has developed an alternative metric that allows CMS oversight on antipsychotic usage in long-term care while increasing access for patients who can benefit. We propose the establishment of a new metric framework based on FDA-approved indications and interdisciplinary clinical decision-making. Project PAUSE has published a framework¹⁰ that would more accurately reflect inappropriate antipsychotic usage and support the ability of surveyors to investigate inappropriate prescribing and use of antipsychotics.

¹⁰ [Project PAUSE: Effective Solutions for Improving Clinical Care in Long-Term Care Settings](#)

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Under this proposed measure, the lead provider would continue to document their clinical rationale for the antipsychotic prescription and the facility's consultant pharmacist would continue to document GDR and medication regimen review (MRR) information. This system creates checks-and-balances based on the professional recommendation of a minimum of two, independent healthcare providers and is focused on patient-centric care and enhancing documentation to support measurement of appropriate and inappropriate use. Additional documentation will also permit groups investigating potential unnecessary use to identify it more easily. Should a surveyor not find the appropriate documentation certifying the need and benefit of antipsychotic utilization, the facility would face potential action related to inappropriately prescribing antipsychotic medications.

Tracking appropriate utilization of antipsychotic medication in long-term care will provide CMS, the Department of Health and Human Services Office of the Inspector General, and Congress with more reliable data to effectively provide oversight on the usage of antipsychotics in long-term care. We encourage Congress, either through statute or less formal communication, to work with CMS to revise the current antipsychotic measure, including a thorough discussion of appropriate utilization and the proposed alternative metric. Incorporating a multidisciplinary review and documentation process, including the prescribing physician and consultant pharmacist, will allow for more accurate assessments of appropriate use while enabling access when clinically indicated and supported by documented risk-assessment of a patient's unique health factors.

Additionally, CMS' current definition of what is a "psychotropic"¹¹ medication is too broad: "A psychotropic drug is *any drug that affects brain activities associated with mental processes and behavior*. These drugs include, *but are not limited to*, drugs in the following categories: (i) Anti-psychotic; (ii) Anti-depressant; (iii) Anti-anxiety; and (iv) Hypnotic [emphasis added]." The italicized sections have caused concern and confusion among operators because they are vague and may be mis-applied to several drugs outside of the identified categories, such as anti-cholinesterase inhibitors. We would like CMS to consider simplifying the definition to: "a psychotropic drug is any drug in the following categories: (i) Anti-psychotic; (ii) Anti-depressant; (iii) Anti-anxiety; and (iv) Hypnotic."

LONG-TERM CARE WORKFORCE MENTAL HEALTH

Finally, we wish to highlight the severe mental health stress and burnout being experienced by health care workers, especially those working in long-term care. A 2020 Kaiser Family Foundation/Washington Post survey of frontline health care workers found that a majority (55%) had feelings of "burnout" and more than one in ten had sought professional mental health services or medicines specific to stress related to COVID-19.

The situation in long-term care is even worse and was challenging before the COVID-19 pandemic. Staff in long-term care facilities face many challenges, including demands of caring for patients numerous and complex medical needs. A 2019 study from the University of Pennsylvania School of Nursing found that nearly a third of all direct-care

¹¹ F758 (Rev. 173, Issued: 11-22-17, Effective: 11-28-17, Implementation: 11-28-17) §483.45(c)(3).

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registered nurses exhibited high level of burnout, and a 2021 study found the median annual turnover rate for nursing home staff is 94 percent.¹² Burnout and the loss of continuity directly impacts patient care. The same study found that nearly three in four nurses surveyed reported missing one or more necessary care task on the last shift due to lack of time or resources.

Ensuring a strong and resilient workforce, especially in health care, is critical; however, solving this issue will not happen instantly. To foster research into empowering the elder care workforce, we recommend formally authorizing the Geriatrics Workforce Enhancement Program (GWEP) and reestablishing the Geriatric Academic Career Awards (GACAs). These programs allow for research into the mental health of elder care workers, strategies that reduce stress experienced by health care workers, and the training of the current and next generation of senior care workers.

CONCLUSION

Project PAUSE appreciates the opportunity to provide information to the Committee on improving mental health care and access for American families, especially those insured by Medicare, Medicaid, CHIP or ACA Marketplace plans. We welcome the opportunity to be a resource to Members and staff as you work to improve behavioral health support and access, especially for individuals living in long-term care and/or those living with dementia. For additional information, please contact Jim Lewis, director of policy and advocacy for the American Society of Consultant Pharmacists at jlewis@ascp.com; or Michael Ward, vice president of policy for the Alliance for Aging Research at mward@agingresearch.org.

Sincerely,

Alliance for Aging Research
AMDA – The Society for Post-Acute and Long-Term Care Medicine
American Association for Geriatric Psychiatry
American Society of Consultant Pharmacists
Caregiver Action Network
National Community Pharmacists Association
National Minority Quality Forum
The Gerontological Society of America

¹² Gandhi, Ashvin, et al. High Nursing Staff Turnover In Nursing Homes Offers Important Quality Information. Health Affairs. 40:3. March 2021. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00957>