

History of Project PAUSE

April 2005: FDA issues “black-box” warning for atypical antipsychotics used for dementia treatment.ⁱ

June 2008: FDA extends “black-box” warning to all antipsychotic medications.ⁱⁱ

June 2009: Senator Chuck Grassley (R-IA) requests the Office of the Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS) to probe antipsychotic usage in nursing homes.ⁱⁱⁱ

May 2011: HHS OIG releases report on use of atypical antipsychotics in nursing home residents.^{iv} The report concludes that there is significant off-label use of antipsychotic drugs and discrepancies in antipsychotic drug claims in Medicare.

May 2012: Senators Kohl (D-WI), Grassley (R-IA) and Blumenthal (D-CT) filed an amendment to curb antipsychotic usage in nursing homes.^v American Medical Association (AMA) House of Delegates passes Policy D-120.951, Appropriate Use of Antipsychotic Medications in Nursing Home Patients.^{vi}

October 2016: CMS publishes the “Mega Rule”.^{vii} The Mega Rule comprehensively revises the conditions required for participation in Medicare and Medicaid for long-term care facilities.

November 2018: CMS updates State Operations Manual to implement Mega Rule.^{viii}

June 2019: American Medical Association (AMA) House of Delegates, in Chicago, IL, 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)”.^{ix}

September 2019: Project PAUSE submits Coalition’s first formal comments to CMS.^x

November 2019: House Ways and Means Committee holds hearing on care for older adults. Project PAUSE submitted testimony.^{xi}

March 2020: Project PAUSE comments on request from Senate Finance Subcommittee on Health Care related to Alzheimer’s Disease.^{xii}

May 2020: Project PAUSE submits comments to Office of Inspector General at the Department of Health and Human Services related inappropriate use of psychotropic drugs.^{xiii}

April 2021: CMS proposes the addition of the “percentage of long-stay residents who got an antipsychotic medication” measure to the value-based purchasing model in the SNF PPS draft rule.^{xiv}

May 2021: HHS OIG releases CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes issue brief outlining numerous issues with the current MDS reporting structured used by the long-stay antipsychotic medication measure and offering recommendations to CMS. CMS concurred with both recommendations from the OIG.^{xv}

June 2021: Project PAUSE submits comments to CMS opposing the inclusion of the “percentage of long-stay residents who got an antipsychotic medication” measure in value-based purchasing.^{xvi}

August 2021: CMS does NOT include “percentage of long-stay residents who got an antipsychotic medication” measure in value-based purchasing. In the final rule, CMS states: “many commenters did not support the Percentage of Long-Stay Residents who got an Antipsychotic Medication measure noting concerns with disincentivizing clinically appropriate access to FDA-approved medications, impact on patient care and outcomes, and that the measure is not NQF-endorsed.”

November 2021: Project PAUSE submits comments to Senate Finance Committee request for feedback on Unmet Mental Health Needs in America.^{xvii}

April 2022: CMS does not propose the addition of the “percentage of long-stay residents who got an antipsychotic medication” measure to value-based purchasing in the annual SNF PPS rulemaking.^{xviii}

June 2022: CMS issues new surveyor guidance, in form of red lines to Appendix PP of State Operations Manual.^{xix}

July 2022: Senate appropriators include report language directing CMS to initiate reforms to this measure citing concerns “that too many residents with neuropsychiatric symptoms who could benefit from FDA-approved treatments do not receive appropriate care and treatment due to a range of factors, including measures that impact the five-star rating system, stigma, and lack of understanding and aware-ness of appropriate treatment.”^{xx}

September 2022: CMS publishes second redline of State Operations Manual Appendix PP.^{xxi}

October 2022: Amendments to Appendix PP of the State Operations Manual enter into effect.^{xxii}

November 2022: HHS OIG issues Long-Term Trends in Psychotropic Drug Use in Nursing Homes finding “psychotropic use in nursing homes was relatively constant from 2011 through 2019. Protecting nursing home residents from the potential harms of psychotropic drugs is essential yet remains challenging without ability to comprehensively determine the scope of these drugs’ use in nursing homes.”^{xxiii}

January 2023: CMS announces additional steps to strengthen nursing home safety and transparency by adding the results of surveys to the Care Compare website and Five-Star Quality Rating System, increasing the quality measure rating thresholds to incentivize and improve quality, and adding measures of staff turnover to inform consumers of the stability of a nursing home’s staff.^{xxiv}

February 2023: CMS establishes a technical expert panel for the “Refinement of the Nursing Home Antipsychotic Medication Measure”.

ⁱ Dorsey, Ray E., et al., Impact of FDA Black Box Advisory on Antipsychotic Medication Use, Arch Intern Med, Jan 11, 2010, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4598075/>. Last visited January 18, 2023.

ⁱⁱ American Psychiatric Association, FDA Extends Black Box Warning to All Antipsychotics, July 18, 2008, available at <https://psychnews.psychiatryonline.org/doi/full/10.1176/pn.43.14.000>. Last visited January 18, 2023.

ⁱⁱⁱ KHN Morning Briefing, Grassley Seeks Probe on Antipsychotic Use in Nursing Homes, June 11, 2009, available at <https://khn.org/morning-breakout/dr00049252/>. Last visited on January 6, 2023.

^{iv} HHS OIG, Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents, May 4, 2011, *available at* <https://oig.hhs.gov/oei/reports/oei-07-08-00150.asp>. Last visited on January 6, 2023.

^v Office of Chuck Grassley, Kohl, Grassley and Blumenthal Seek to Cut Misuse of Antipsychotics, May 22, 2012, *available at* <https://www.grassley.senate.gov/news/news-releases/kohl-grassley-and-blumenthal-seek-cut-misuse-antipsychotics>. Last visited on January 6, 2023.

^{vi} American Medical Association, Resolution 703 – Mandating Reporting of all Antipsychotic Drug Use in Nursing Home Residents, *available at* <https://www.ama-assn.org/system/files/a22-ref-cmte-g-preliminary-doc.pdf>. Last visited on January 10, 2023.

^{vii} CMS Final Regulation, Medicare and Medicaid Programs; Reform for Long-Term Care Facilities, *available at* <https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities>. Last visited on January 6, 2023.

^{viii} CMS Final Regulation, Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, November 28, 2016, *available at* <https://www.govinfo.gov/content/pkg/FR-2016-10-04/pdf/2016-23503.pdf>. Last visited on January 23, 2023.

^{ix} American Medical Association, Resolution 708 – Access to Psychiatric Treatment in Long-Term Care, *available at* <https://www.ama-assn.org/system/files/2020-01/a19-resolutions.pdf>. Last visited on January 23, 2023.

^x Alliance for Aging Research, Re: [CMS-3347-P] Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions To Promote Efficiency, and Transparency, September 26, 2019, *available at* <https://www.agingresearch.org/wp-content/uploads/2019/10/CMS-LTC-sign-on-comment-9-16-19.pdf>. Last visited on January 10, 2023.

^{xi} Alliance for Aging Research, Statement for Hearing on “Caring for Aging Americans”; Submitted to the Committee on Ways and Means, November 29, 2019, *available at* <https://www.agingresearch.org/wp-content/uploads/2020/04/Caring-for-Aging-Americans-Testimony-Final.pdf>. Last visited on January 10, 2023.

^{xii} Project PAUSE, Re: Subcommittee on Health Care Seeks Feedback on Actions to Address Alzheimer’s Disease, March 13, 2020, *available at* https://cdn.ymaws.com/www.ascp.com/resource/resmgr/docs/prc/project_pause_subcommittee_o.pdf. Last visited on January 10, 2023.

^{xiii} Alliance for Aging Research, Response to OIG Inquiry, May 26, 2020, *available at* <https://www.agingresearch.org/wp-content/uploads/2020/07/Project-PAUSE-Response-to-OIG-Inquiry.pdf>. Last visited on January 10, 2023.

^{xiv} Federal Register, Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2022; and Technical Correction to Long-Term Care Facilities Physical Environment Requirements, August 4, 2021, *available at* <https://www.federalregister.gov/documents/2021/08/04/2021-16309/medicare-program-prospective-payment-system-and-consolidated-billing-for-skilled-nursing-facilities>. Last visited on January 10, 2023.

^{xv} HHS OIG, CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes, May 2021, *available at* <https://oig.hhs.gov/oei/reports/OEI-07-19-00490.pdf>. Last visited on January 10, 2023.

^{xvi} Project Pause, Re: Request for Information (RFI) on Proposals to Address Unmet Mental Health

Needs, November 15, 2021, *available at* https://www.agingresearch.org/wp-content/uploads/2021/11/Project-PAUSE-Sign-on-Comment-Letter-Senate-Finance-RFI-on-Mental-Health_11.15.21.pdf. Last visited on January 10, 2023.

^{xvii} Project Pause, Re: Request for Information (RFI) on Proposals to Address Unmet Mental Health Needs, November 15, 2021, *available at* https://www.agingresearch.org/wp-content/uploads/2021/11/Project-PAUSE-Sign-on-Comment-Letter-Senate-Finance-RFI-on-Mental-Health_11.15.21.pdf. Last visited on January 10, 2023.

^{xviii} Federal Register, Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2023; Changes to the Requirements for the Director of Food and Nutrition Services and Physical Environment Requirements in Long-Term Care Facilities, August 3, 2022, *available at* <https://www.federalregister.gov/documents/2022/08/03/2022-16457/medicare-program-prospective-payment-system-and-consolidated-billing-for-skilled-nursing-facilities>. Last visited on January 10, 2023.

^{xix} CMS, State Operations Manual, Appendix PP – Guidance to Surveyors for Long Term Care Facilities, June 2022 (revised October 2022), *available at* <https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf>. Last visited January 18, 2023.

^{xx} Senate Committee on Appropriations, Explanatory Statement for Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 2023, *available at* <https://www.appropriations.senate.gov/imo/media/doc/LHHSFY23REPT.pdf>. Last visited on January 10, 2023.

^{xxi} CMS, State Operations Manual, Appendix PP – Guidance to Surveyors for Long Term Care Facilities, June 2022 (revised October 2022), *available at* <https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf>. Last visited January 18, 2023.

^{xxii} CMS Regulations and Guidance, State Operations Manual, Appendix PP – Guidance to Surveyors for Long Term Care Facilities, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltc.pdf. Last visited on January 10, 2023.

^{xxiii} HHS OIG, Long-Term Trends of Psychotropic Drug Use in Nursing Homes, November 2022, *available at* <https://oig.hhs.gov/oei/reports/OEI-07-20-00500.pdf>. Visited on January 10, 2023.

^{xxiv} CMS, Updates to the Nursing Home Care Compare Website and Five Star Quality Rating System, Adjusting Quality measure Ratings Based on Erroneous Schizophrenia Coding, and Posting Citations Under Dispute, January 18, 2023, *available at* <https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-states/updates-nursing-home-care-compare-website-and-five-star-quality-rating-system-adjusting-quality>. Last visited January 18, 2023.