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OFF-LABEL USE OF ANTIPSYCHOTIC MEDICATION IN NURSING FACILITIES

This memorandum provides the history of the establishment of the Centers for Medicare and Medicaid Services (CMS) National Partnership to Improve Dementia Care in Nursing Homes (National Partnership), public reporting of antipsychotic use, efforts made to reduce antipsychotic use, and data on the off-label use of antipsychotic medications in nursing facilities.

History of National Partnership

The Omnibus Budget Reconciliation Act of 1987 (also referred to as OBRA '87 or the Nursing Home Reform Law) established a regulatory structure designed to transform how nursing home residents lived. OBRA '87 required every nursing home to “provide care and services in order for each resident to attain or maintain his/her highest practical level of physical, mental, and psychosocial well-being.”

The Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services released a [report](#) in 2011 discussing widespread off-label use of antipsychotic medications among nursing home residents. The OIG report indicated 83.0 percent of atypical antipsychotic drug claims were for elderly nursing home residents who did not have a diagnosis for which antipsychotic medications were approved by the Food and Drug Administration (FDA).

Concern over antipsychotic use in nursing homes was expressed by nursing home advocates and others. The U.S. House Ways and Means Committee expressed apprehension regarding the high Medicare expenditures for antipsychotic drugs, and questioned whether the drugs were resulting in positive outcomes and providing value for patients. In early 2012, in response to the OIG report and these questions and concerns, CMS established the National Partnership. The National Partnership was a public-private collaboration focused on improving the quality of life for nursing home residents through improved comprehensive approaches to the psychosocial and behavioral health needs of residents, especially those with dementia. The initial focus of the National Partnership was the reduction of the use of antipsychotic medications, but the overall goal was to enhance the use of non-pharmacological approaches and person-centered dementia practices.

The initial goal set by the National Partnership was a 15.0 percent reduction in antipsychotic medication use. Data from the last three quarters of calendar year 2011 was used as a baseline. The national average for the percentage of long-stay residents who received an antipsychotic during this time frame was 23.8 percent.

Public Reporting of Antipsychotic Medication Use

In July 2012, CMS began public reporting of antipsychotic medication use for each nursing home on the Nursing Home Compare (NHC) website. Two new measures were posted on the NHC website: an incidence measure that assesses the percentage of short-stay residents given antipsychotic medication after admission to the nursing home, and a prevalence measure used to track the progress of the National Partnership that assesses the percentage of long-stay residents receiving an antipsychotic medication. Both measures were used for star rating calculation on the Five-Star Quality Rating System.

Efforts to Reduce Antipsychotic Use and Improve Dementia Care

To reduce unnecessary antipsychotic use, CMS directed surveyors to speak with physicians, nurse practitioners, and other prescribers about the process used to decide whether to use antipsychotic medications in residents with dementia. Surveyors were also to identify whether there was effective communication among the nursing staff, medical team, behavioral health teams, prescribers, consultant pharmacist, and family regarding prescribing decisions.

CMS worked with quality improvement organizations and Advancing Excellence Local Area Networks for Excellence (LANES) to locate existing groups or establish new state coalitions for dementia care in every state. The groups shared best practices, hosted educational programs, engaged in peer-to-peer mentoring, and conducted outreach to facilities and groups not yet involved in the initiative.

Surveyor interpretive guidance for care of a resident with dementia and the unnecessary use of medications was revised as part of the work of the National Partnership and distributed through a Survey and Certification Letter ([S & C 13-35](#)) in May 2013.

A CMS Quality, Safety, and Oversight Group (QSO) policy memorandum issued February 14, 2020 ([QSO 20-11-NH](#)), describes two new optional [toolkits](#) developed by CMS through the Civil Money Penalty Reinvestment Program (CMPRP) to aid nursing homes in the care of residents with dementia and to reduce common infections experienced by nursing home residents. One toolkit, the DREAM Toolkit, is intended to help nursing facilities better understand the importance of high-quality sleep and help them improve the quality of life and quality of care for residents living with dementia. The Developing a Restful Environment Action Manual (DREAM) Toolkit provides education and person-centered, non-pharmacological practical interventions to help promote the high-quality sleep necessary for optimal cognitive and physical functioning, especially for residents with dementia.

Data on Antipsychotic Use

An April 11, 2014, CMS Survey and Certification policy memorandum ([S & C 14-19-NH](#)) addressed to State Survey Agency Directors contains the Interim Report on the CMS National Partnership for Quarter 4 of 2011 through Quarter 1 of 2014 and provides further detail on the National Partnership's history, its activities, the early progress of its initiatives, and future plans. According to the Interim Report, approximately one in four nursing home residents received at least one antipsychotic medication, and many of those residents had dementia. The FDA issued a "black box" warning in 2005 and 2008 related to the use of antipsychotics in older adults with dementia due to a number of serious side effects and an increased risk of death in this

population. However, the report notes antipsychotics continued to be used commonly to treat behavioral or psychological symptoms of dementia. The Interim Report noted possible reasons for the high use of antipsychotic medications included a lack of staff training, the perception that non-pharmacological interventions to address the behaviors may be less effective or too time-consuming to be part of standard nursing home care for most residents, and the association of lower registered nurse staffing levels with higher antipsychotic use.

The Interim Report ranked Kansas 45th in Quarter 4 of 2013 in the quarterly prevalence of antipsychotic use for long-stay residents and 48th for short-stay residents, where a lower numerical ranking was considered better. According to the Interim Report, over a period of 18 months, the efforts of the National Partnership reduced the national prevalence of antipsychotic use in long-stay nursing home residents by 15.1 percent, with a prevalence rate decrease from 23.8 percent to 20.2 percent. Every CMS region showed some improvement. Incidence rates for short-term residents also improved. CMS then set a new national goal of reducing the use of antipsychotic medications in long-stay nursing home residents by 25.0 percent by the end of 2015, and 30.0 percent by the end of 2016.

Dementia Care Survey Pilots

A March 27, 2015, CMS Survey and Certification letter ([S & C 15-31-NH](#)) contains the final report of a five-state CMS Focused Dementia Care Survey Pilot undertaken in 2014, the pilot process used, conclusions based on post-pilot analysis, and future steps. CMS started a focused dementia care survey in 2014 to thoroughly examine the process for prescribing antipsychotic medication and assess compliance with other federal requirements related to dementia care practices in nursing homes.

The survey was conducted to gain better insight on surveyor knowledge, skills, and attitudes and to determine how the survey process could be streamlined to efficiently and accurately identify and cite deficient survey practices and recognize successful dementia care programs. States were invited to participate in the pilot to test new surveyor worksheets and processes focused on dementia care. California, Minnesota, New York, Illinois, and Louisiana participated in the pilot, with each state completing four focused surveys and an observation visit between July and September 2014.

After review of surveyor feedback and data analysis from the first survey pilot, CMS revised the survey tools and expanded the focused survey pilot by inviting states to conduct the surveys in fiscal year (FY) 2015 on a voluntary basis using the revised tools. Surveys were conducted in California, Illinois, Mississippi, Missouri, Nebraska, and Texas. The expansion project placed greater focus on a targeted effort to improve surveyor effectiveness in citing poor dementia care and overutilization of antipsychotic medications that occurred in FY 2014. Whenever possible, CMS assisted volunteer states in identifying dementia care experts to accompany surveyors for the first survey.

On June 3, 2016, [S & C Letter 16-28-NH](#) was sent to state survey agency directors and contained a CMS-released second report summarizing the activities of the National Partnership following the release of S & C Policy Memorandum 14-19-NH. The report also describes the results of the Focused Dementia Care Surveys conducted in FY 2015 and the conclusions derived from post-survey data analysis. The report covers calendar year (CY) 2014 Quarter 2 through CY 2015 Quarter 3 and indicates a decrease of 27.0 percent in the prevalence of antipsychotic medication use in long-stay nursing home residents since the beginning of the National Partnership, to a national prevalence of 17.4 percent in FY 2015 Quarter 3. Kansas

ranked 47th in the nation in the prevalence of antipsychotic medication use in long-stay nursing home residents in CY 2015 Quarter 3, with a prevalence rate of 20.4 percent. CMS conducted additional surveys in FY 2016 to expand upon the work of the focused survey pilot, targeting nursing homes that continued to have high rates of antipsychotic medication use.

Late Adopter Facilities

According to a QSO policy memorandum issued on March 1, 2019 ([QSO 19-07-NH](#)), CMS has seen a reduction of 38.9 percent in long-stay nursing home residents who were receiving an antipsychotic medication since 2011. However, through the National Partnership, CMS identified approximately 1,500 facilities that had not improved their antipsychotic medication utilization rates for long-stay nursing home residents (referred to as late adopters). CMS notified the late adopter facilities of their identification in December 2017. Data on the antipsychotic use in late adopter facilities from 2011 Quarter 4 through 2021 Quarter 4 (updated July 30, 2021), including Kansas facilities, is available on the CMS website.¹ The goal set by CMS for the late adopter facilities is to decrease antipsychotic medication use by 15.0 percent for long-stay residents by the end of 2019, using the prior baseline rate (2011 Quarter 4).

A CMS [quarterly data report](#) (updated July 30, 2021) specific to the progress of the late adopters indicates, in 2011 Quarter 4, 21.4 percent of long-stay nursing home residents living in a nursing home identified as a late adopter were receiving an antipsychotic medication. As of 2020 Quarter 4, the report notes a decrease of 20.9 percent to a national prevalence among late adopters of 16.9 percent. As of 2020 Quarter 4, Kansas ranks 19th among the states regarding antipsychotic use in late adopter facilities. Kansas has 59 facilities identified as late adopters. The quarterly data report contains data on each state's antipsychotic use in late adopter facilities for 2011 Quarter 4 through 2021 Quarter 4.

As of January 2019, citations were issued for 235 late adopter nursing homes for two or more instances of noncompliance with federal regulations related to unnecessary medications or psychotropic medications since January 1, 2016, that had not shown improvement in their long-stay antipsychotic medication rates. The late adopter facilities face enhanced oversight and are subject to enforcement remedies if determined not to be in substantial compliance with requirements for Chemical Restraints, Dementia Care, or Psychotropic Medications during a survey. In approximately one year, CMS was to reevaluate this enhanced oversight policy among all late-adopter homes to determine whether to continue or modify efforts, or both.

All Nursing Facilities—2020 Data

According to a CMS antipsychotic use data report for 2020 Quarter 4 (updated July 30, 2021), CMS is tracking the progress of the National Partnership by reviewing publicly reported measures.² The National Partnership's official measure is the percentage of long-stay nursing home residents who are receiving an antipsychotic medication, excluding residents diagnosed with schizophrenia, Huntington's Disease, or Tourette Syndrome.

As previously noted, in 2011 Quarter 4, 23.9 percent of long-stay nursing home residents were receiving an antipsychotic medication. The data report notes there has been a decrease of

1 <https://www.cms.gov/files/document/late-adopter-antipsychotic-use-state-2020q4-updated-07302021.xlsx>

2 <https://www.cms.gov/files/document/antipsychotic-medication-use-data-report-2020q4-updated-07302021.pdf>

39.4 percent to a national prevalence of 14.5 percent in 2020 Quarter 4. A CMS data report on antipsychotic use by state and by facility for 2020 Quarters 1 through 4 (updated July 30, 2021) notes the percent of long-stay residents who received antipsychotic medications and the percent of short-stay residents who newly received antipsychotic medications for each state facility.³

3 <https://www.cms.gov/files/document/antipsychotic-use-state-2020q1-2020q4-updated-07302021.xlsx>