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# ANTIPSYCHOTIC DRUG USE

HHS Has Initiatives to  
Reduce Use among  
Older Adults in  
Nursing Homes, but  
Should Expand Efforts  
to Other Settings

# GAO Highlights

Highlights of [GAO-15-211](#), a report to congressional requesters

## Why GAO Did This Study

Dementia affects millions of older adults, causing behavioral symptoms such as mood changes, loss of communication, and agitation. Concerns have been raised about the use of antipsychotic drugs to address the behavioral symptoms of the disease, primarily due to the FDA's boxed warning that these drugs may cause an increased risk of death when used by older adults with dementia and the drugs are not approved for this use.

GAO was asked to examine psychotropic drug prescribing for older adult nursing home residents. In this report, GAO examined (1) to what extent antipsychotic drugs are prescribed for older adults with dementia living inside and outside nursing homes, (2) what is known from selected experts and published research about factors contributing to the such prescribing, and (3) to what extent HHS has taken action to reduce the use of antipsychotic drugs by older adults with dementia. GAO analyzed multiple data sources including 2012 Medicare Part D drug event claims and nursing home assessment data; reviewed research and relevant federal guidance and regulations; and interviewed experts and HHS officials.

## What GAO Recommends

GAO recommends that HHS expand its outreach and educational efforts aimed at reducing antipsychotic drug use among older adults with dementia to include those residing outside of nursing homes by updating the National Alzheimer's Plan. HHS concurred with this recommendation.

View [GAO-15-211](#). For more information, contact Katherine M. Iritani, (202) 512-7114, [iritanik@gao.gov](mailto:iritanik@gao.gov).

January 2015

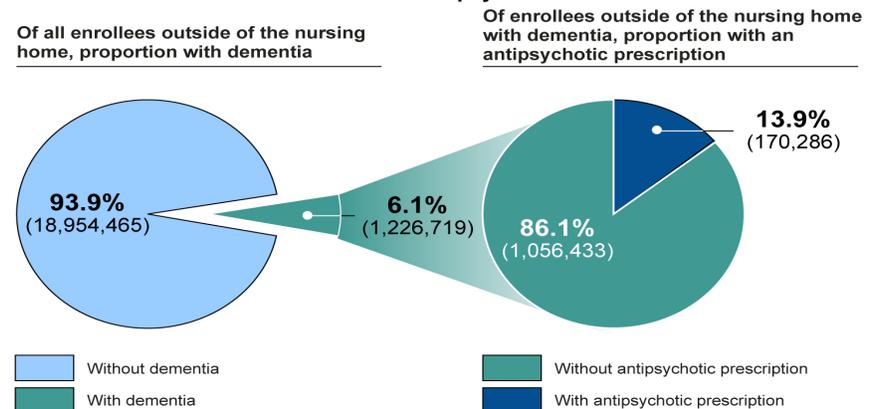
## ANTIPSYCHOTIC DRUG USE

### HHS Has Initiatives to Reduce Use among Older Adults in Nursing Homes, but Should Expand Efforts to Other Settings

## What GAO Found

Antipsychotic drugs are frequently prescribed to older adults with dementia. GAO's analysis found that about one-third of older adults with dementia who spent more than 100 days in a nursing home in 2012 were prescribed an antipsychotic, according to data from Medicare's prescription drug program, also known as Medicare Part D. Among Medicare Part D enrollees with dementia living outside of a nursing home that same year, about 14 percent were prescribed an antipsychotic. (See figure.)

**Proportion of Older Adult Medicare Part D Enrollees Outside of the Nursing Home Diagnosed with Dementia Who Were Prescribed an Antipsychotic in 2012**



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) Medicare Part D data. | GAO-15-211

Note: GAO excluded individuals diagnosed with schizophrenia or bipolar disorder because the Food and Drug Administration (FDA) has approved certain antipsychotic drugs for the treatment of these conditions.

Experts and research identified patient agitation or delusions, as well as certain setting-specific characteristics, as factors contributing to the prescribing of antipsychotics to older adults. For example, experts GAO spoke with noted that antipsychotic drugs are often initiated in hospital settings and carried over when older adults are admitted to a nursing home. In addition, experts and research have reported that nursing home staff levels, particularly low staff levels, lead to higher antipsychotic drug use.

Agencies within the Department of Health and Human Services (HHS) have taken several actions to address antipsychotic drug use by older adults in nursing homes, as described in HHS's National Alzheimer's Plan; however, none have been directed to settings outside of nursing homes, such as assisted living facilities or individuals' homes. While the National Alzheimer's Plan has a goal to improve dementia care for all individuals regardless of residence, HHS officials said that efforts to reduce antipsychotic use have not focused on care settings outside nursing homes, though HHS has done work to support family caregivers in general. Stakeholders GAO spoke to indicated that educational efforts similar to those provided for nursing homes should be extended to other settings. Extending educational efforts to caregivers and providers outside of the nursing home could help lower the use of antipsychotics among older adults with dementia living both inside and outside of nursing homes.

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## Abbreviations

ACL	Administration for Community Living
AHRQ	Agency for Healthcare Research and Quality
CERT	Center for Education & Research on Therapeutics
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
MBSF	Master Beneficiary Summary File
MDS	Long Term Care Minimum Data Set
NDC	national drug code
NIH	National Institutes of Health
NPPES	National Plan and Provider Enumeration System
OIG	Office of Inspector General
PASRR	Preadmission Screening and Resident Review
PDE	Medicare Part D Prescription Drug Event
QIO	Quality Improvement Organization

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January 30, 2015

The Honorable Ron Johnson  
Chairman  
The Honorable Thomas R. Carper  
Ranking Member  
Committee on Homeland Security and Governmental Affairs  
United States Senate

The Honorable Susan M. Collins  
Chairman  
Special Committee on Aging  
United States Senate

Dementia affected almost 15 percent of older adults in the United States in 2010, according to an estimate from the RAND Corporation.<sup>1</sup> RAND estimated that the total monetary cost for caring for individuals with dementia was between \$157 billion and \$215 billion, of which the Medicare program paid around \$11 billion.<sup>2</sup> Furthermore, RAND estimated that dementia costs will more than double by 2040 due to the aging of the American population. While dementia is most commonly associated with a decline in memory, it can also cause changes in mood or personality, loss of communication, and, at times, agitation or aggression. These behavioral symptoms can become challenging for caregivers, both at home and in institutions such as nursing homes. To manage these behaviors, antipsychotic drugs are sometimes prescribed. Although experts indicate that an appropriate rate of prescribing of antipsychotic drugs cannot be determined given that the clinical decision to prescribe antipsychotics is based on individual patient factors, many

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<sup>1</sup>This estimate applies to adults aged 71 and older. See Michael D. Hurd, et. al, "Monetary Costs of Dementia in the United States," *New England Journal of Medicine*, vol. 368, no. 14 (2013).

Dementia is not a specific illness, but a term that describes symptoms including memory decline. Specific types of dementia, and diseases that can cause dementia, include Alzheimer's disease (the most common type), vascular dementia, and Parkinson's disease dementias.

<sup>2</sup>Monetary costs include out-of-pocket spending, Medicare spending, nursing home spending, and costs of in-home care. The higher estimate includes forgone wages from informal, unpaid care.

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believe that prescribing rates for these drugs, particularly for nursing home residents with dementia, have been too high.

Concerns have been raised about the use of antipsychotic drugs to address behavioral symptoms—such as agitation or aggression—in older adults. While a large proportion of prescriptions for antipsychotic drugs in this population are used to treat behavioral symptoms, these drugs are not approved for this use, and antipsychotic drugs have health risks.<sup>3</sup> In 2011, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) reported that a large percentage—88 percent—of a 2007 sample of 1.4 million Medicare claims for newer antipsychotic drugs for older adult nursing home residents was associated with a dementia diagnosis. The Food and Drug Administration (FDA)—tasked with approving drugs to be marketed in the United States—has not approved these drugs to treat the behavioral symptoms of dementia, although it has generally approved antipsychotic drugs to treat schizophrenia and bipolar disorder.<sup>4</sup> Furthermore, these drugs have been found to cause falls and other adverse events, including an increased risk of death, among older adults with a diagnosis of dementia.<sup>5</sup> All antipsychotic drugs carry an FDA-required boxed warning stating that they are associated with an increased risk of death when used to treat older adults with dementia-related psychosis.<sup>6</sup> Physicians are not prohibited from prescribing antipsychotic drugs in the presence of dementia despite the boxed warning, nor are they prohibited generally from prescribing a drug for uses other than what the FDA has approved. Otherwise known as off-label prescribing, this practice is common in the

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<sup>3</sup>We define older adults as those around the age of 65 and older.

<sup>4</sup>Certain antipsychotic drugs are also FDA-approved for the treatment of Tourette syndrome and adjunct treatment of major depressive disorder.

<sup>5</sup>When the FDA or drug manufacturers determine that a drug may lead to death or serious injury when used in certain situations, FDA may require that the product's label include a boxed warning.

<sup>6</sup>Psychosis is characterized by a loss of touch with reality and can be expressed through delusions and hallucinations. While the boxed warning is specific to dementia-related psychosis, antipsychotic drugs are often used to treat other behavioral symptoms of dementia. For the purposes of our report, we examine antipsychotic use among older adults with dementia, broadly.

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United States, and Medicare Part D covers drugs prescribed off-label in some cases.<sup>7</sup>

Less is known about antipsychotic prescribing in settings outside of the nursing home, but one study estimated that out of a sample of older adults with dementia living outside of a nursing home, close to one in five took an antipsychotic between 2002 and 2004.<sup>8</sup> The federal government has an interest in improving dementia care for individuals living both inside and outside nursing homes. The National Alzheimer's Project Act, enacted in January 2011, required HHS to establish the National Alzheimer's Project to create and maintain an integrated plan to overcome Alzheimer's disease, including related dementias.<sup>9</sup> HHS developed its first National Alzheimer's Plan in 2012, and it includes a number of actions to improve systems of care and service delivery to individuals with dementia.<sup>10</sup>

You asked us to examine psychotropic drug prescribing for older adult nursing home residents. In this report, we examine (1) to what extent antipsychotic drugs are prescribed for older adults with dementia living in and outside of nursing homes and what Medicare Part D plans paid for these drugs; (2) what is known from selected experts and published

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<sup>7</sup>Medicare Part D is an optional outpatient prescription drug benefit offered by Medicare—the federally financed health insurance program for persons aged 65 and over, individuals under age 65 with certain disabilities, and individuals with end-stage renal disease administered by HHS's Centers for Medicare & Medicaid Services (CMS). CMS contracts with private companies—plan sponsors—to provide benefits under Medicare Part D. Antipsychotic drugs—a type of psychotropic drug—are also sometimes paid for through Medicare Parts A (hospital benefit) and B (physician office benefit).

Medicare Part D reimbursement criteria require that drugs be used for medically accepted conditions; this includes FDA-approved conditions as well as conditions, which may or may not be off-label, supported by three specific medical compendia: the American Hospital Formulary Service Drug Information, the United States Pharmacopoeia-Drug Information, and the DrugDEX Information System.

<sup>8</sup>Y. Rhee, J. G. Cernansky, L. L. Emanuel, C. G. Chang, and J. W. Shega, "Psychotropic Medication Burden and Factors Associated with Antipsychotic Use: An Analysis of a Population-Based Sample of Community-Dwelling Older Persons with Dementia," *Journal of the American Geriatrics Society*, vol. 59, no. 11 (2011).

<sup>9</sup>Pub. L. No. 111-375, § 2(d)(2), 124 Stat. 4100 (Jan. 4, 2011).

<sup>10</sup>While the National Alzheimer's Plan specifically mentions Alzheimer's disease, it also addresses related dementias, as required under the act. The National Alzheimer's Plan is updated annually.

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research about factors contributing to the prescribing of antipsychotic drugs to older adults with dementia; and (3) to what extent HHS has taken action to reduce the use of antipsychotic drugs in older adults with dementia.

To estimate the extent to which older adults residing inside and outside of nursing homes are prescribed antipsychotic drugs, we first analyzed Medicare Part D Prescription Drug Event (PDE) data for individuals with dementia in 2012.<sup>11</sup> We used the Medicare Part D PDE data because Medicare is the primary source of insurance coverage for individuals over the age of 65, and approximately 63 percent of Medicare beneficiaries were enrolled in Medicare Part D in 2012. To identify individuals living in nursing homes, we combined the PDE claims data with 2012 data from the Long Term Care Minimum Data Set (MDS),<sup>12</sup> which includes nursing home assessments for all individuals living in nursing homes, regardless of insurance coverage. We also used data from the Medicare Master Beneficiary Summary File (MBSF),<sup>13</sup> as well as the Medicare Part D Risk File to identify diagnoses, including dementia diagnoses and diagnoses for certain conditions for which FDA has approved the use of antipsychotics drugs.<sup>14</sup> We excluded from our estimates individuals with dementia also diagnosed with one of these FDA-approved conditions for antipsychotic drugs—schizophrenia and bipolar disorder. We define an individual as having been prescribed an antipsychotic drug if they were prescribed at least one prescription for an antipsychotic drug during the year, regardless of how many days' supply are covered by the prescription. Within the nursing home population, our analysis of PDE claims specifically identified those with a long stay in the nursing home—

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<sup>11</sup>The PDE data contain pharmacy claims for all prescription drugs dispensed to Medicare Part D beneficiaries.

We define locations outside of the nursing home as any location an individual may reside that it is not a nursing home. This may include assisted living facilities or an individual's home.

<sup>12</sup>The MDS contains information from nursing-home resident assessments for all Medicare or Medicaid certified nursing homes, regardless of payer. In 2012, over 15,600 nursing homes were Medicare and Medicaid certified and included in the MDS. Medicaid is the joint federal-state program that finances health care for low-income individuals.

<sup>13</sup>MBSF includes data on enrollment, spending, and use of services for all Medicare beneficiaries.

<sup>14</sup>The Medicare Part D Risk File contains enrollee information such as age, gender, and diagnoses from the previous year.

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defined by the Centers for Medicare & Medicaid Services (CMS) as more than 100 days—because drugs for individuals with short stays—100 days or less—are generally covered under Medicare Part A, not Part D. We identified antipsychotic prescriptions in the PDE claims data by examining relevant national drug codes (NDC) using a list of generic names for antipsychotic drugs.<sup>15</sup> We disaggregated the data to examine certain characteristics, such as gender, age, and geographic location.

To supplement our analysis of the Medicare Part D data for the nursing home population, we also analyzed data on antipsychotic prescribing and diagnoses among nursing home residents available in the MDS. This allowed us to look at a more comprehensive population of nursing home residents—all residents in a Medicare or Medicaid certified nursing home—and to examine prescribing rates by length of stay.<sup>16</sup> For this analysis, we determined an individual was prescribed an antipsychotic drug if any nursing home assessment during 2012 indicated the resident took an antipsychotic drug during the previous 7 days. In addition to excluding residents with dementia also diagnosed with schizophrenia and bipolar disorder, we also excluded residents with Tourette syndrome, a condition for which FDA has approved the use of certain antipsychotics, as well as Huntington's disease, a condition for which CMS guidance has recognized antipsychotics as an acceptable treatment.<sup>17</sup> Individuals with dementia and at least one of these diagnoses accounted for about 7 percent of nursing home residents with dementia overall.

To identify what Medicare Part D plans paid for antipsychotic drugs prescribed to older adults with dementia in 2012, we identified individuals with dementia using the Medicare Part D Risk File, and calculated plan payments for those enrollees using the PDE claims data. We also calculated plan payments for the most commonly prescribed antipsychotic drugs, and used the National Plan and Provider Enumeration System (NPPES) to identify the breakdown of prescriber specialties listed on

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<sup>15</sup>NDCs uniquely identify specific drug products for a given manufacturer.

<sup>16</sup>Nearly all of the 15,700 nursing homes providing long term care services in the United States participated in the Medicare and Medicaid programs in 2012.

<sup>17</sup>We were unable to exclude Medicare Part D enrollees with Tourette syndrome and Huntington's disease for the Medicare PDE analysis because the Medicare Part D Risk File does not contain information on whether an enrollee has been diagnosed with these conditions.

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antipsychotic drug claims under Medicare Part D in 2012 to calculate the share of plan payments for prescriptions from the specialties with the most antipsychotic prescribing for individuals with dementia.<sup>18</sup> For more details on the data analyses, see appendix I.

We ensured the reliability of the MDS data, Medicare PDE claims data, Medicare Part D Risk File data, MBSF data, and NPPES data used in this report by performing appropriate electronic data checks, reviewing relevant documentation, and interviewing officials and representatives knowledgeable about the data, where necessary. We found the data were sufficiently reliable for the purpose of our analyses.

To examine what is known from selected experts and published research about factors contributing to the prescribing of antipsychotic drugs to older adults with dementia, we interviewed experts in the field of dementia care and conducted a literature review. We used a snowball sampling approach to identify industry, provider, and advocacy groups, as well as research experts, with experience or work on the subject of antipsychotic drug use among older adults. We interviewed two to five groups within each category of expert groups and asked them about contributing factors. We also conducted a literature review to identify original research on factors associated with prescribing antipsychotic drugs to older adults. We searched for relevant articles published in peer-reviewed journals from January 2009 through March 2014 and excluded international research. We also included articles published within our timeframe that were identified through our interviews. We found a total of 42 articles that met our inclusion criteria; after reviewing those articles, we found contributing factors cited in 18 articles. For more details on the literature review and a list of the articles identified, see appendix II.

To identify the extent to which HHS has taken action to reduce prescribing of antipsychotic drugs to older adults, we spoke with officials from agencies within HHS, including CMS, FDA, the Administration for Community Living (ACL),<sup>19</sup> the National Institutes of Health's (NIH)

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<sup>18</sup>NPPES is a list of all Medicare providers, including unique provider identifiers, maintained by CMS.

<sup>19</sup>ACL was created in 2012 to bring together key HHS organizations and offices—the Administration on Aging, the Office on Disability, and the Administration on Developmental Disabilities—into a single agency to provide support for individuals in the community with functional needs, such as seniors with dementia.

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National Institute on Aging and National Institute of Mental Health, and the Agency for Healthcare Research and Quality (AHRQ). We also reviewed relevant federal regulations, CMS nursing home guidance, agency Web pages, and other federal documents, such as the National Alzheimer’s Plan.

We conducted this performance audit from January 2014 through January 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

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### Antipsychotic Drug Classification and FDA-Approved Uses

Antipsychotic drugs are classified into two sub-groups. The first group, or generation, of antipsychotic drugs—also known as “conventional” or “typical” antipsychotic drugs—was developed in the mid-1950s. Examples include haloperidol (Haldol®) and loxapine (Loxitane®). The second generation of antipsychotic drugs, known as “atypical” antipsychotics, was developed in the 1980s. Examples include aripiprazole (Abilify®) and risperidone (Risperdal®). Atypical antipsychotics became more popular upon their entry into the market due to the initial belief that these drugs caused fewer side effects than the conventional antipsychotics. Each antipsychotic drug has its own set of FDA-approved indications.<sup>20</sup> The vast majority of antipsychotic drugs are FDA-approved for the treatment of schizophrenia, and most atypical antipsychotic drugs are FDA-approved for the treatment of bipolar disorder. In addition, some antipsychotics are FDA-approved for the treatment of Tourette syndrome. CMS guidance to state nursing home surveyors also recognizes antipsychotics as an acceptable treatment for conditions for which the drugs have not been FDA-approved, such as for the treatment of Huntington’s disease.

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<sup>20</sup>FDA-approved indications may include, for example, use of a drug to treat a particular diagnosed condition, or symptom, in specific populations and under certain conditions.

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In 2005, FDA recognized the risks associated with atypical antipsychotic drugs and required those drugs to have a boxed warning, citing a higher risk of death related to use among those with dementia. In 2008, FDA recognized similar risks for conventional antipsychotic drugs and required the same boxed warning. Besides the risks described in the boxed warning, use of antipsychotic drugs carries risks of other side effects, such as sedation, hypotension, movement disorders, and metabolic syndrome issues.

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## Treatment Approaches for Behavioral Symptoms of Dementia

Clinical guidelines consistently suggest the use of antipsychotic drugs for the treatment of the behavioral symptoms of dementia only when other, non-pharmacological attempts to ameliorate the behaviors have failed, and the individuals pose a threat to themselves or to others.<sup>21</sup> For example, AMDA—The Society for Post-Acute and Long-Term Care Medicine suggests first assessing the scope and severity of the behavior and identifying any environmental triggers for the behavior. A medical evaluation may determine whether the behavioral symptoms are associated with another medical condition, such as under-treated arthritis pain or constipation. In its clinical guideline, AMDA cited conflicting evidence surrounding the effectiveness of antipsychotic drugs in treating the behavioral symptoms of dementia.<sup>22</sup> It noted one evidence review that found significant improvement in symptoms with the treatment of certain atypical antipsychotic drugs, but also noted that other reviews signaled there were no significant differences attributable to atypical antipsychotic drugs.

Other non-pharmacological interventions that can be attempted prior to the use of antipsychotic drugs may focus on emotions, sensory

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<sup>21</sup>See American Psychiatric Association, *Practice Guideline for the Treatment of Patients With Alzheimer's Disease and Other Dementias* (October 2007); American Geriatrics Society, "Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults," *Journal of the American Geriatrics Society*, vol. 60, no. 4 (2012); and American Medical Directors Association, *Excerpts from the Dementia in the Long Term Care Setting Clinical Practice Guideline: American Medical Directors Association* (Columbia, Md.: 2012).

<sup>22</sup>American Medical Directors Association, *Excerpts from the Dementia in the Long Term Care Setting Clinical Practice Guideline*.

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stimulation, behavior management, or other psychosocial factors.<sup>23</sup> An example of an emotion-oriented approach is Reminiscence Therapy, which involves the recollection of past experiences through old materials with the intention of enhancing group interaction and reducing depression. An example of a sensory stimulation approach is Snoezelen Therapy, which typically involves introducing the individual to a room full of objects designed to stimulate multiple senses, including sight, hearing, touch, taste, and smell. This intervention is based on the theory that behavioral symptoms may stem from sensory deprivation. A 2012 white paper published by the Alliance for Aging Research and the Administration on Aging, a part of the ACL, noted that advancements have been made with regards to the evidence base supporting some non-pharmacological interventions, but that evidence-based interventions are not widely implemented.<sup>24</sup> Experts referenced in the white paper identified the need for clearer information about the interventions, such as a system to classify what interventions exist and who might benefit from those interventions. Experts also noted that additional research is needed to develop effective interventions.

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## Federal Nursing Home Standards and Regulations

Federal law requires nursing homes to meet federal quality and safety standards, set by CMS, to participate in the Medicare and Medicaid programs. CMS regulations require nursing homes to ensure that residents' drug therapy regimens are free from unnecessary drugs, such as medications provided in excessive doses, for excessive durations, or without adequate indications for use.<sup>25</sup> Nursing facility staff must assess each resident's functional capacity upon admission to the facility and

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<sup>23</sup>See Department of Veterans Affairs Health Services Research & Development Service, *A Systematic Evidence Review of Non-pharmacological Interventions for Behavioral Symptoms of Dementia* (Washington, D.C.: March 2011).

<sup>24</sup>K. Maslow, *Translating Innovation to Impact: Evidence-Based Interventions to Support People with Alzheimer's Disease and Their Caregivers at Home and in the Community*, a report prepared at the request of the Alliance for Aging Research, the Administration on Aging, and MetLife Foundation (Washington, D.C.: The Alliance for Aging Research, September 2012).

<sup>25</sup>42 C.F.R. § 483.25(l). Federal law also requires that nursing homes protect and promote residents' rights to be free from chemical restraints, defined as any drug used for discipline or convenience and not required to treat the resident's medical symptoms. 42 U.S.C. § 1395i-3(c)(1)(A)(ii).

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periodically thereafter, and provide each resident a written care plan.<sup>26</sup> Based on these assessments, nursing homes must ensure that antipsychotics are prescribed only when necessary to treat a specific condition diagnosed and documented in the patient's record, and that residents who use antipsychotic drugs receive gradual dose reductions and behavioral interventions, unless clinically contraindicated. Part of the nursing home survey process, otherwise known as nursing home inspections, involves audits of these care plans and assessments.<sup>27</sup>

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**Approximately  
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About one-third of older adult Medicare Part D enrollees with dementia who spent over 100 days in a nursing home were prescribed an antipsychotic drug in 2012. Among those Medicare Part D enrollees with dementia who spent no time in a nursing home in 2012, we found that about 14 percent were prescribed an antipsychotic. In total, Medicare Part D plans paid roughly \$363 million in 2012 for antipsychotic drugs prescribed for older adult Medicare Part D enrollees with dementia.

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<sup>26</sup>In addition to any other requirements a state may have established, it must operate a Preadmission Screening and Resident Review (PASRR) program, approved by CMS as part of its state Medicaid plan, that provides for the evaluation of all individuals with serious mental illness who apply to reside in Medicaid certified nursing homes. According to CMS, if PASRR recommends that a nursing home is the appropriate setting, necessary treatment, such as antipsychotic drugs, should be specifically listed on the PASRR recommendations. If an individual does not have a PASRR recommendation for antipsychotic drugs, additional scrutiny may be triggered if an antipsychotic drug is prescribed.

<sup>27</sup>All nursing homes that participate in the Medicare and Medicaid programs are subject to periodic surveys to ensure that they are in compliance with federal quality standards. CMS contracts with state survey agencies to conduct the surveys. Surveys must include an adequate number of residents with dementia who are receiving an antipsychotic drug.

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**Roughly One-third of Older Adult Nursing Home Residents with Dementia Were Prescribed an Antipsychotic Drug in 2012**

We found that about 33 percent of Medicare beneficiaries with dementia who were enrolled in a Part D plan and had a long stay in a nursing home—defined as over 100 cumulative days—were prescribed an antipsychotic in 2012.<sup>28</sup> (See table 1.) We also found that prescribing rates for Medicare Part D enrollees with dementia who were nursing home residents varied somewhat by resident characteristic:

- Male enrollees were slightly more likely to have been prescribed an antipsychotic drug than female enrollees—about 36 percent and 32 percent, respectively.
- The prescribing rate declined as Medicare Part D enrollee age increased. For example, about 41 percent of those Medicare Part D enrollees aged 66 to 74 received an antipsychotic prescription, compared to 29 percent of those enrollees aged 85 and older who were prescribed an antipsychotic drug.
- The prescribing rate for antipsychotic drugs was highest for enrollees in the South, and lowest for enrollees in the West.

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<sup>28</sup>Medicare Part D prescriptions for short-stay nursing home enrollees—enrollees with 100 days or less in the nursing home—may be low because often Medicare Part A covers drugs administered during short, post-acute stays in nursing homes.

**Table 1: Number and Percent of Older Adult Medicare Part D Enrollees Diagnosed with Dementia Who Had a Long Stay in a Nursing Home and Were Prescribed an Antipsychotic in 2012, by Characteristic**

		Enrollees with dementia in the long-stay nursing home setting <sup>a</sup>		
		Number without antipsychotic prescription	Number with antipsychotic prescription	Percent with antipsychotic prescription
<b>Total</b>		<b>268,486</b>	<b>131,480</b>	<b>33%</b>
<b>Gender</b>	Female	206,215	95,911	32
	Male	62,271	35,569	36
<b>Age</b>	66-74	28,888	19,842	41
	75-84	89,131	51,014	36
	85+	150,467	60,624	29
<b>Census location</b>	Midwest	73,906	33,743	31
	Northeast	68,648	31,120	31
	South	93,026	52,938	36
	West	32,906	13,679	29

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) Medicare Part D data. | GAO-15-211

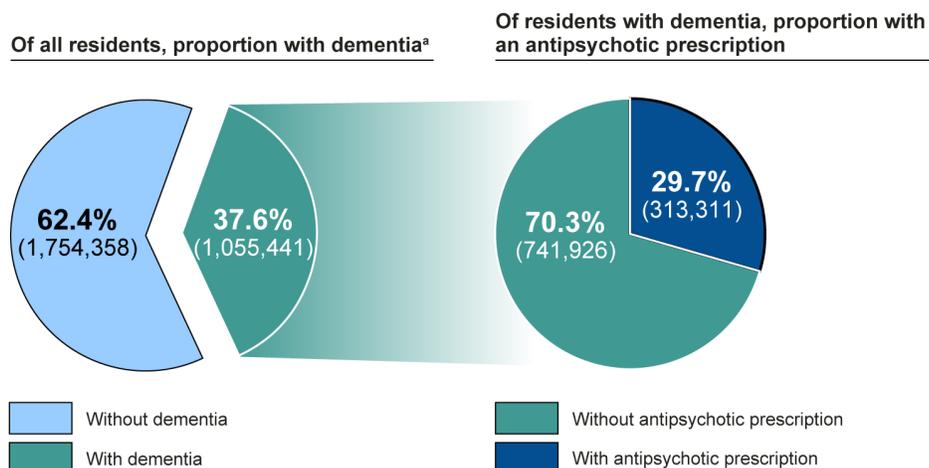
Notes: Percentages are rounded to the nearest whole number. Enrollees outside of the 50 states and the District of Columbia were excluded, as were enrollees with less than 12 months of Medicare Part D enrollment, those whose Medicare coverage began on or after January 1, 2011, and those who passed away in 2012. We included only those that lived through 2012 because antipsychotics can be used in the hospice or palliative setting to make patients more comfortable at the end of their lives. We also excluded enrollees with dementia who were also diagnosed with schizophrenia or bipolar disorder because FDA has approved certain antipsychotics for the treatment of these two conditions. Diagnostic information was identified using Medicare Part D Risk File data, and includes only diagnoses from the previous year. Enrollees are considered as having dementia if one of the following diagnoses were present in the 2012 Medicare Part D Risk File: a general dementia diagnosis, a diagnosis of Alzheimer's disease, or a diagnosis of Parkinson's disease.

<sup>a</sup>If a Medicare Part D enrollee had a nursing home stay that was longer than 100 days, they were considered a long-stay nursing home enrollee; data on all other enrollees with shorter stays in nursing homes are not included in this table.

We found slightly lower rates of antipsychotic drug prescribing when we restricted our analysis to those enrollees with three or more 30-day supply prescriptions during 2012. Specifically, about 28 percent of long-stay Medicare Part D enrollees with dementia were given three or more 30-day supply prescriptions for an antipsychotic drug over the course of 2012. We also found that the majority of prescriptions given to those long-stay Medicare Part D enrollees with dementia—about 68 percent—were for seven or more 30-day supplies of the drug, while only 3 percent were for less than one 30-day supply.

Consistent with the findings for Medicare Part D enrollees, our analysis of MDS data showed that approximately 30 percent of all older adult nursing home residents—regardless of enrollment in Medicare Part D—with a dementia diagnosis were prescribed an antipsychotic drug at some point during their 2012 nursing home stay.<sup>29</sup> (See fig. 1.) Residents with dementia accounted for a significant proportion of all nursing home residents. In 2012, about 38 percent, or almost 1.1 million of the 2.8 million nursing home residents that year, were diagnosed with dementia.

**Figure 1: Proportion of Older Adult Nursing Home Residents Diagnosed with Dementia Who Were Prescribed an Antipsychotic in 2012**



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) nursing home assessment data. | GAO-15-211

Notes: Data on antipsychotic drugs were missing for 204 residents with dementia. Residents in facilities outside of the 50 states and the District of Columbia were excluded, as were residents who passed away in the facility in 2012. We included only those that lived through 2012 because antipsychotics can be used in the hospice or palliative setting to make residents more comfortable at the end of their lives. We also excluded residents with dementia who were also diagnosed with schizophrenia, bipolar disorder, Huntington's disease, and Tourette syndrome because FDA has approved certain antipsychotics for the treatment of schizophrenia, bipolar disorder, and Tourette syndrome, and CMS guidance recognizes antipsychotics as an acceptable treatment for Huntington's disease. Diagnostic information was identified using all assessments with a target date in 2012 for a given resident. The initiation of the antipsychotic prescription could have occurred prior to the nursing home stay or during the nursing home stay.

<sup>a</sup>A resident is considered as having dementia if one of the following diagnoses were present on any of the resident's assessments in 2012: a general dementia diagnosis, a diagnosis of Alzheimer's disease, or a diagnosis of Parkinson's disease.

<sup>29</sup>To examine this more comprehensive population of nursing home residents, we identified prescribing rates based on nursing home assessments through the MDS.

Examining this more comprehensive database of nursing home residents also allowed us to compare the antipsychotic drug prescribing rates of long-stay residents and short-stay residents—those residents who spent 100 days or less in the nursing home. The proportion of residents diagnosed with dementia who were prescribed an antipsychotic drug was greater for long-stay residents than for short-stay residents (about 33 percent versus 23 percent, respectively). (See table 2.) Variation in prescribing rates across resident characteristics was similar to the variation found in the Medicare Part D enrollee long-stay nursing home population.

**Table 2: Antipsychotic Drug Prescribing among Older Adult Nursing Home Residents with a Dementia Diagnosis, 2012**

		Residents with dementia <sup>a</sup>		
		Number without antipsychotic prescription	Number with antipsychotic prescription	Percent with antipsychotic prescription
<b>All</b>		<b>741,926</b>	<b>313,311</b>	<b>30%</b>
<b>Length of stay<sup>b</sup></b>	Short stay	285,570	86,471	23
	Long stay	456,356	226,840	33
<b>Gender</b>	Female	520,729	208,516	29
	Male	221,145	104,785	32
<b>Age</b>	65-74	75,251	43,080	37
	75-84	240,158	115,043	32
	85+	429,247	155,188	27
<b>Census location</b>	Midwest	199,391	77,804	28
	Northeast	177,365	72,313	29
	South	259,121	126,145	33
	West	106,049	37,049	26

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) nursing home assessment data. | GAO-15-211

Notes: Percentages are rounded to the nearest whole number. The gender of some residents was unidentified, and those residents are not included in the gender breakdown. Residents in facilities outside of the 50 states and the District of Columbia were excluded, as were residents who passed away in the facility in 2012. We included only those that lived through 2012 because antipsychotics can be used in the hospice or palliative setting to make residents more comfortable at the end of their lives. We also excluded residents with dementia who were also diagnosed with schizophrenia, bipolar disorder, Huntington's disease, and Tourette syndrome because FDA has approved certain antipsychotics for the treatment of schizophrenia, bipolar disorder, and Tourette syndrome, and CMS guidance recognizes antipsychotics as an acceptable treatment for Huntington's disease. Diagnostic information was identified using all assessments with a target date in 2012 for a given resident. The initiation of the antipsychotic prescription could have occurred prior to the nursing home stay or during the nursing home stay.

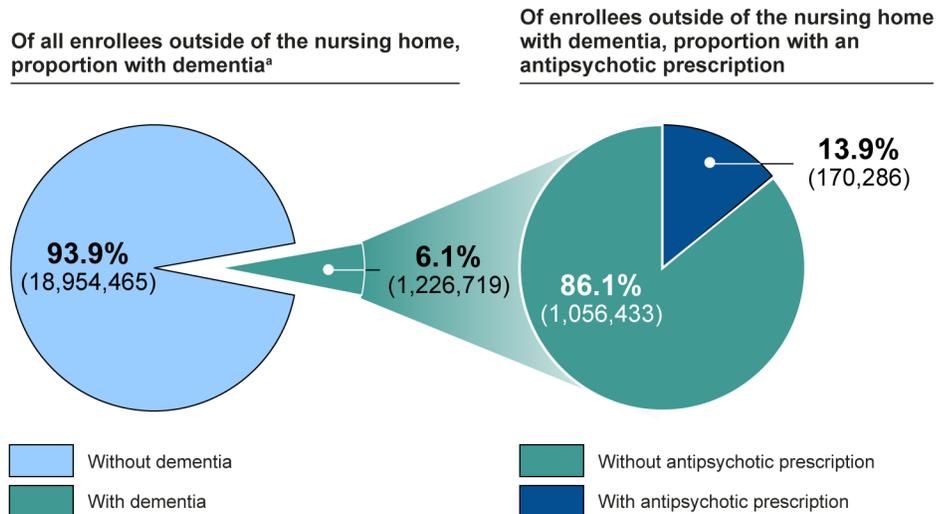
<sup>a</sup>A resident is considered as having dementia if one of the following diagnoses were present on any of the resident's assessments in 2012: a general dementia diagnosis, a diagnosis of Alzheimer's disease, or a diagnosis of Parkinson's disease.

<sup>b</sup>If a resident had a nursing home stay that was longer than 100 days, they were considered a long-stay resident; all other residents were considered short-stay residents.

## One in Seven Older Adult Medicare Part D Enrollees with Dementia Living Outside of Nursing Homes Were Prescribed an Antipsychotic Drug in 2012

Of those Medicare Part D enrollees with dementia in settings outside of the nursing home, about one in seven (14 percent) were prescribed an antipsychotic. (See fig. 2.) Roughly 1.2 million of the 20.2 million older adult Medicare Part D enrollees living outside of a nursing home in 2012 had a diagnosis of dementia—just above 6 percent.

**Figure 2: Proportion of Older Adult Medicare Part D Enrollees Outside of the Nursing Home Diagnosed with Dementia Who Were Prescribed an Antipsychotic in 2012**



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) Medicare Part D data. | GAO-15-211

Notes: Enrollees outside of the 50 states and the District of Columbia were excluded, as were enrollees with less than 12 months of Medicare Part D enrollment, those whose Medicare coverage began on or after January 1, 2011, and those who passed away in 2012. We included only those that lived through 2012 because antipsychotics can be used in the hospice or palliative setting to make patients more comfortable at the end of their lives. We also excluded enrollees with dementia who were also diagnosed with schizophrenia or bipolar disorder because FDA has approved certain antipsychotics for the treatment of these two conditions. Diagnostic information was identified using Medicare Part D Risk File data, and includes only diagnoses from the previous year.

<sup>a</sup>Enrollees are considered as having dementia if one of the following diagnoses were present in the 2012 Medicare Part D Risk File: a general dementia diagnosis, a diagnosis of Alzheimer's disease, or a diagnosis of Parkinson's disease.

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The rate of antipsychotic drug prescribing among older adult Medicare Part D enrollees with dementia was lower for those living outside of nursing homes, compared to those living in nursing homes, given that residents of nursing homes are generally sicker than those living outside of nursing homes. We also found that the pattern of variation in antipsychotic drug prescribing for Medicare Part D enrollees outside of a nursing home for certain characteristics was different from the pattern of variation found in the nursing home population.

- The proportion of Medicare Part D enrollees outside of nursing homes diagnosed with dementia who were prescribed an antipsychotic drug was higher for older enrollees—the opposite of the pattern found in the nursing home setting. (See table 3.)
- The prescribing rate was also higher for female enrollees outside of the nursing home than for male enrollees, whereas the opposite was true in the nursing home setting.
- The prescribing rate for enrollees with dementia outside of the nursing home changed less depending on enrollee location than those in nursing homes.

**Table 3: Number and Percent of Older Adult Medicare Part D Enrollees Diagnosed with Dementia Who Spent No Time in a Nursing Home and Were Prescribed an Antipsychotic in 2012, by Characteristic**

		Enrollees with dementia outside of the nursing home setting		
		Number without antipsychotic prescription	Number with antipsychotic prescription	Percent with antipsychotic prescription
<b>Total</b>		<b>1,056,433</b>	<b>170,286</b>	<b>14%</b>
<b>Gender</b>	Female	677,304	119,779	15
	Male	379,129	50,507	12
<b>Age</b>	66-74	238,542	33,328	12
	75-84	468,323	73,171	14
	85+	349,568	63,787	15
<b>Census location</b>	Midwest	225,473	30,913	12
	Northeast	204,389	34,316	14
	South	384,800	65,196	15
	West	241,771	39,861	14

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) Medicare Part D data. | GAO-15-211

Notes: Percentages are rounded to the nearest whole number. Enrollees outside of the 50 states and the District of Columbia were excluded, as were enrollees with less than 12 months of Medicare Part D enrollment, those whose Medicare coverage began on or after January 1, 2011, and those who passed away in 2012. We included only those that lived through 2012 because antipsychotics can be used in the hospice or palliative setting to make patients more comfortable at the end of their lives. We also excluded enrollees with dementia who were also diagnosed with schizophrenia or bipolar disorder because FDA has approved certain antipsychotics for the treatment of these two conditions. Diagnostic information was identified using Medicare Part D Risk File data, and includes only diagnoses from the previous year. Enrollees are considered as having dementia if one of the following diagnoses were present in the 2012 Medicare Part D Risk File: a general dementia diagnosis, a diagnosis of Alzheimer's disease, or a diagnosis of Parkinson's disease.

We found slightly lower rates of antipsychotic drug prescribing for Medicare Part D enrollees outside of the nursing home when we restricted our analysis to those enrollees with three or more 30-day supply prescriptions. Specifically, about 11 percent of enrollees outside of the nursing home received three or more prescriptions for antipsychotic drugs over the course of 2012. About 58 percent of antipsychotic prescriptions for Medicare Part D enrollees with dementia living outside of a nursing home were for seven or more 30-day supplies of the drug, while only 3 percent were for less than a 30-day supply.

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Medicare Part D Plan  
Payments for  
Antipsychotic Drugs  
Prescribed to Older Adult  
Enrollees with Dementia  
Totalled \$363 Million in  
2012

Medicare Part D plans paid roughly \$363 million in 2012 for antipsychotic drugs used by Medicare Part D enrollees with dementia aged 66 and older.<sup>30</sup> (See table 4.) Medicare Part D spending on antipsychotic drugs for Medicare Part D enrollees living outside of a nursing home with a dementia diagnosis totaled almost \$171 million in 2012, the same as spending for long-stay nursing home enrollees with dementia. Payments for short-stay nursing home enrollees may be low because often Medicare Part A covers drugs administered during short, post-acute stays in nursing homes. Medicare Part D plans consistently spent more than double on antipsychotic prescriptions for female enrollees than for male enrollees; as reported in table 1, the number of female Medicare Part D enrollees using antipsychotic drugs was also over two times that of males.

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<sup>30</sup>Medicare Part D plans paid almost \$1.2 billion in 2012 for antipsychotic drugs used by Medicare Part D enrollees aged 66 and older, regardless of dementia diagnosis. We excluded new enrollees, including all 65-year-olds, because the Medicare Part D Risk File did not have diagnostic data for these groups.

**Table 4: Medicare Part D Plan Payments for Older Adult Enrollees Who Used an Antipsychotic in 2012, by Setting and Diagnosis Category**

In millions

		Enrollees in the long-stay nursing home setting <sup>a</sup>		Enrollees outside of the nursing home setting		Total, including short-stay nursing home	
		Total spending on antipsychotic drugs	Enrollees with dementia <sup>b</sup>	Total spending on antipsychotic drugs	Enrollees with dementia	Total spending on antipsychotic drugs	Enrollees with dementia
	<b>All</b>	<b>\$367</b>	<b>\$171</b>	<b>\$748</b>	<b>\$171</b>	<b>\$1,185</b>	<b>\$363</b>
<b>Gender</b>	Female	259	124	521	122	830	261
	Male	109	47	227	49	356	102
<b>Age</b>	66-74	132	34	446	44	611	83
	75-84	138	69	210	72	373	151
	85+	97	68	91	55	201	130

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) Medicare Part D data. | GAO-15-211

Notes: Enrollees in and outside of the nursing home cannot be directly compared because the severity of dementia—and thus, the level of treatment acuity—needed for enrollees in the nursing home is much greater than that for enrollees outside of the nursing home. Enrollees outside of the 50 states and the District of Columbia were excluded, as were enrollees with less than 12 months of Medicare Part D enrollment, those whose Medicare coverage began on or after January 1, 2011, and those who passed away in 2012. We included only those that lived through 2012 because antipsychotics can be used in the hospice or palliative setting to make patients more comfortable at the end of their lives. Diagnostic information was identified using Medicare Part D Risk File data, and includes only diagnoses from the previous year.

<sup>a</sup>If a Medicare Part D enrollee had a nursing home stay that was longer than 100 days, they were considered a long-stay nursing home enrollee; all other enrollees who spent time in a nursing home were considered short-stay enrollees.

<sup>b</sup>Enrollees are considered as having dementia if one of the following diagnoses were present in the 2012 Medicare Part D Risk File: a general dementia diagnosis, a diagnosis of Alzheimer’s disease, or a diagnosis of Parkinson’s disease. For this dementia-specific calculation, we excluded enrollees with dementia who were also diagnosed with schizophrenia or bipolar disorder because FDA has approved certain antipsychotics for the treatment of these two conditions.

Internal medicine, family medicine, and psychiatry or neurology physicians prescribed the greatest proportion of antipsychotic drug prescriptions for older adult Medicare Part D enrollees with dementia—about 82 percent in total. Antipsychotic drugs prescribed by these specialties also made up about 82 percent of the Medicare Part D plan payments for antipsychotic drugs—almost \$298 million in plan payments. Antipsychotic prescriptions from internal medicine physicians comprised 36 percent of Medicare Part D plan payments for antipsychotic drugs, while family medicine and psychiatry or neurology prescriptions comprised about 30 and 16 percent, respectively. Nurse practitioner and

physician assistant prescriptions collectively accounted for almost 5 percent of antipsychotic drug claim payments, while the remaining 13 percent encompassed many specialties.<sup>31</sup>

Quetiapine Fumarate, Risperidone, and Olanzapine were the most commonly prescribed antipsychotic drugs for older adult Medicare Part D enrollees with dementia in 2012, comprising approximately \$246 million in plan payments. (See table 5.) Haloperidol and Aripiprazole were also commonly prescribed; these two drugs were prescribed to almost 9 and 6 percent of Medicare Part D enrollees with dementia, respectively.

**Table 5: Number and Percent of Older Adult Medicare Part D Enrollees with Dementia and Antipsychotic Drug Prescriptions, and Medicare Part D Plan Payments for Those Prescriptions in 2012, by Antipsychotic Drug**

Antipsychotic drug	Number	Percent	Payments in millions
Quetiapine Fumarate*	146,868	48.7%	\$158
Risperidone*	100,108	33.2	24
Olanzapine*	38,458	12.7	64
Haloperidol	26,761	8.9	1
Aripiprazole*	18,015	6.0	80
Ziprasidone HCL*	5,031	1.7	10
All Other	9,270	3.0	5

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) Medicare Part D data. | GAO-15-211

\*denotes atypical antipsychotic drugs

Notes: Percentages are rounded to the nearest tenth of a percent and do not add up to 100, suggesting that some enrollees had prescriptions for multiple antipsychotic drugs. Enrollees outside of the 50 states and the District of Columbia were excluded, as were enrollees with less than 12 months of Part D enrollment, those whose Medicare coverage began on or after January 1, 2011, and those who passed away in 2012. We included only those that lived through 2012 because antipsychotics can be used in the hospice or palliative setting to make patients more comfortable at the end of their lives. We also excluded enrollees with dementia who were also diagnosed with schizophrenia or bipolar disorder because FDA has approved certain antipsychotics for the treatment of these two conditions. Diagnostic information was identified using Medicare Part D Risk File data, and includes only diagnoses from the previous year. Enrollees are considered as having dementia if one of the following diagnoses were present in the 2012 Medicare Part D Risk File: a general dementia diagnosis, a diagnosis of Alzheimer's disease, or a diagnosis of Parkinson's disease. This table does not include prescriptions for enrollees with a short stay in the nursing home because prescriptions during a short stay may be covered by Medicare Part A.

<sup>31</sup> About 5 percent of prescriptions contained a provider identifier that did not match with the NPPES data, and 1 percent of prescriptions contained a provider identifier for which the taxonomy code listed did not match a taxonomy code listed by the Washington Publishing Company, the creator of healthcare provider taxonomy codes.

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## Experts and Research Commonly Cited Certain Patient and Setting-Specific Factors Contributing to the Prescribing of Antipsychotic Drugs to Older Adults

Experts we spoke with and research we reviewed commonly identified certain factors that are specific to the patient that contribute to antipsychotic prescribing, such as patient agitation or delusions. Experts and research also identified certain contributing factors that are specific to settings, such as to nursing homes or hospitals.

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## Experts and Research Identified Patient-Specific Factors, Such As Agitation or Delusions, That Contribute to the Decision to Prescribe Antipsychotic Drugs

The majority of experts we spoke with and some research articles we reviewed highlighted agitation, aggression, or exhibiting a risk to oneself or others as factors that contribute to the decision to prescribe antipsychotics. For example, in a study examining the MDS from 1999 to 2006 in eight states, 51 percent of aggressive nursing home residents diagnosed with dementia were prescribed antipsychotic drugs in 2006, as opposed to 39 percent of residents with behavioral symptoms but who were not aggressive during that same time period.<sup>32</sup> The study suggested that aggressive residents may have been more likely to be prescribed antipsychotics because of the greater risk of injury associated with the aggressive behavior. This is consistent with findings from our analysis of nursing home assessment data; we found that, of residents diagnosed with dementia and documented as being a risk to themselves or others, 61 percent had an antipsychotic drug prescription in 2012.

Many experts we interviewed identified other situations that may warrant the use of antipsychotics despite their risk, such as patients experiencing frightening delusions or hallucinations that cause the patient to act out in ways that may be violent or harmful. Several experts noted that individuals experiencing these psychotic and other behaviors may be suffering from distress and are more likely to be prescribed antipsychotic

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<sup>32</sup>S. Crystal, M. Olfson, C. Huang, H. Pincus, and T. Gerhard, "Broadened Use of Atypical Antipsychotics: Safety, Effectiveness, and Policy Challenges," *Health Affairs*, vol. 28, no. 5 (2009).

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drugs to ease their distress and improve their quality of life.<sup>33</sup> For example, individuals may injure themselves or strike another resident or staff member because of delusions that these people intend to kill them. A few research articles identified psychotic behaviors as a contributing factor. For instance, one study that examined medical records of more than 200 nursing home residents with dementia found that 47 percent of residents who were on an antipsychotic also had a diagnosis of psychosis.<sup>34</sup>

The research we reviewed also cited other specific patient characteristics associated with higher antipsychotic use in dementia patients. Patient characteristics such as age, gender, race or ethnicity, and psychiatric diagnoses were associated with higher antipsychotic prescribing in several articles. For example, in one study of nursing home assessments and Medicaid drug claims from seven states, researchers found that nursing home residents with psychiatric co-morbidities, such as anxiety and depression without psychosis, were more likely to be prescribed antipsychotic drugs.<sup>35</sup> Male gender was also mentioned as a patient characteristic associated with higher antipsychotic prescribing in three research articles.<sup>36</sup> In our analyses of 2012 Medicare data, males had a higher prescribing rate in the nursing home, while females had a higher rate outside of the nursing home. Finally, one article found that black nursing home residents were more likely to be prescribed antipsychotic

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<sup>33</sup>Psychotic behaviors may be associated with multiple conditions, including schizophrenia or dementia. Antipsychotic drugs are FDA-approved for the treatment of schizophrenia but not approved for the treatment of behavioral symptoms of dementia.

<sup>34</sup>Healthcare Management Solutions, LLC and the Meyers Primary Care Institute at the University of Massachusetts Medical School. *Antipsychotic Drug Use Project Final Report* (Columbia, Md.: January 2013).

<sup>35</sup>See J. A. Lucas, S. Chakravarty, J. R. Bowblis, T. Gerhard, E. Kalay, E. K. Paek, and S. Crystal, "Antipsychotic Medication Use in Nursing Homes: A Proposed Measure of Quality," *International Journal of Geriatric Psychiatry* (2014).

<sup>36</sup>See Lucas, et al, "Antipsychotic Medication Use"; Y. Chen, B. A. Briesacher, T. S. Field, J. Tija, D. T. Lau, and J. H. Gurwitz, "Unexplained Variation across US Nursing Homes in Antipsychotic Prescribing Rates," *Archives of Internal Medicine*, vol. 170, no.1 (2010); and P. Kamble, H. Chen, J. T. Shere, and R. R. Aparasu, "Use of Antipsychotics Among Elderly Nursing Home Residents with Dementia in the U.S.: An Analysis of National Survey Data," *Drugs & Aging*, vol. 26, no. 6 (2009).

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drugs, while another article found that black residents were less likely to receive them when compared to white residents.<sup>37</sup>

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## Experts and Research Identified Setting-Specific Factors That Contribute to Antipsychotic Prescribing

Experts and research identified factors within the setting that an individual visits or resides in, such as nursing homes or hospitals, as contributing to the decision to prescribe antipsychotic drugs to older adults. Among nursing homes, experts and research cited factors, including the culture of the facility, the level of staff training and education, and the number of staff at the nursing home, as contributing to the decision to prescribe antipsychotic drugs to older adults. Specifically, nursing home leadership—such as administrators and medical directors—and culture were cited by half of the experts and two of the research articles. An expert told us that when the leadership of the nursing home believes it is broadly acceptable to provide antipsychotic drugs to residents with dementia, this belief spreads throughout the facility. One study examining variation in antipsychotic use in nursing homes looked at the pharmacy claims and nursing home assessments of more than 16,000 residents in 1,257 nursing homes.<sup>38</sup> The study found that new nursing home residents admitted to facilities with high antipsychotic prescribing rates were 1.4 times more likely to receive antipsychotics, even after controlling for patient-specific factors.

In addition to nursing home culture and leadership, many experts and two research articles identified staff or prescriber education and training on antipsychotic prescribing for individuals with dementia as affecting antipsychotic drug prescribing. One industry group we spoke with indicated that physician training specifically regarding older adults with dementia in nursing homes and knowledge of related federal regulations are often lacking. Similarly, a study in 68 nursing homes in Connecticut examining knowledge of nursing home leaders and staff, who often set the tone for prescribing antipsychotic drugs and observing patients' behavioral symptoms, found most of the certified nursing assistants—96 percent—were not aware of the serious risks to residents that can

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<sup>37</sup>See Lucas, et al, "Antipsychotic Medication Use" and Chen, et al, "Unexplained Variation Across U.S. Nursing Homes."

<sup>38</sup>See Chen, et al, "Unexplained Variation across U.S. Nursing Homes."

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result from antipsychotic use.<sup>39</sup> The study also found that 56 percent of direct-care staff believed medications worked well to manage resident behavior. Another article reported that antipsychotic drug prescribing for individuals with dementia decreased from 20.3 to 15.4 percent in one nursing home after the implementation of an educational in-service training designed to reduce the inappropriate use of antipsychotic prescribing and increase documentation of non-pharmacological interventions.<sup>40</sup> In expert interviews, education of staff was identified as a factor that can contribute to minimizing unnecessary antipsychotic prescribing. One provider group noted that, in order to reduce antipsychotic use, a facility would need to invest in professional training for staff in a way that provides information about adequate alternatives to antipsychotic drugs.

Nursing home staffing levels, specifically low staff levels, were also cited as a contributing factor to antipsychotic drug use in one research article and by a few experts. For example, one study examined more than 5,000 nursing homes and 561,000 residents by linking 2009 and 2010 prescription drug claims to the Nursing Home Compare database to identify a nationwide pattern of antipsychotic drug use.<sup>41</sup> The study found the nursing homes with the highest quintiles of antipsychotic drug use had significantly less staff than those with the lowest quintiles.<sup>42</sup> An expert group noted that nursing homes with less staff may not have enough activities and oversight for the patients, which in turn may make the nursing home residents susceptible to higher antipsychotic drug use.

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<sup>39</sup>C. A. Lemay, K. M. Mazor, T. S. Field, J. Donovan, A. Kanaan, B. A. Briesacher, S. Foy, L. R. Harrold, J. H. Gurwitz, and J. Tjia, "Knowledge of and Perceived Need for Evidence-based Education about Antipsychotic Medications among Nursing Home Leadership and Staff," *Journal of the American Medical Directors Association*, vol. 14, no.12 (2013).

<sup>40</sup>K. Watson-Wolfe, E. Galik, J. Klinedinst, and N. Brandt, "Application of the Antipsychotic Use in Dementia Assessment Audit Tool to Facilitate Appropriate Antipsychotic Use in Long Term Care Residents with Dementia," *Geriatric Nursing*, vol. 35 (2014).

<sup>41</sup>Nursing Home Compare is a consumer tool designed to help individuals choose a nursing home for themselves or someone for whom they are caring by displaying information related to the quality of specific nursing homes.

<sup>42</sup>B. A. Briesacher, J. Tjia, T. Field, K. M. Mazor, J. L. Donovan, A. O. Kanaan, and J. H. Gurwitz, "Nationwide Variation in Nursing Home Antipsychotic Use, Staffing and Quality of Care," *Pharmacoepidemiology and Drug Safety*, vol. 21 (2012).

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In addition, the majority of experts we spoke with told us that entering a nursing home from a hospital is a factor leading to higher antipsychotic prescribing in the nursing home. These experts agreed that antipsychotic drugs are often initiated in hospital settings and carried over to nursing home settings. One industry group we spoke with noted that individuals with dementia go to the hospital frequently and can be prescribed an antipsychotic drug if they exhibit disruptive behavior. Another industry group attributed the actual prescribing of antipsychotic drugs to hospital care culture and stated that the prescribing of antipsychotics is a common practice in hospitals for treating individuals with dementia. A research study that examined the medical charts of 73 residents in seven nursing homes found 84 percent of the residents that had been admitted to the nursing home from the hospital were admitted on at least one psychoactive medication—including antipsychotics.<sup>43</sup>

Finally, experts we spoke with indicated that caregivers' frustration with the behavior of individuals with dementia can lead to requests for antipsychotic drugs. For example, an advocacy group we spoke with mentioned that a caregiver may request an antipsychotic drug for an individual with dementia in an effort to keep them in the home. The individual with dementia may not recognize their relative, which can cause them agitation. To keep the individual calm so that they can stay in the home and not be placed in a nursing home, an antipsychotic medication may be prescribed. Representatives from another provider group explained that when an individual with dementia has an unmet need, they may also appear to be in distress, which may cause the caregiver to become frustrated because they do not know how to relieve this distress.

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<sup>43</sup>V. A. Molinari, D. A. Chiriboga, L. G. Branch, J. Schinka, L. Schonfeld, L. Kos, W. L. Mills, J. Krok, and K. Hyer, "Reasons for Psychiatric Medication Prescription for New Nursing Home Residents," *Aging and Mental Health*, vol. 15, no. 7 (2011).

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## HHS Agencies' Actions Focused on Reducing Antipsychotic Drug Use by Older Adults with Dementia Target Nursing Home Residents, Not Those in Other Settings

HHS agencies, including CMS, AHRQ, and NIH, have taken actions to address antipsychotic drug use by older adults with dementia in nursing homes. However, HHS has done little to address antipsychotic drug use among older adults with dementia living in settings outside of the nursing home.

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## HHS Has Several Initiatives Focused on Reducing Antipsychotic Drug Use by Older Adult Nursing Home Residents

Under the National Plan to Address Alzheimer's Disease, HHS has a goal to expand support for people with Alzheimer's disease and their families with emphasis on maintaining the dignity, safety, and rights for those suffering from this disease.<sup>44</sup> To reach this goal, HHS outlined several actions, including monitoring, reporting, and reducing the use of antipsychotics drugs by older adults in nursing homes. CMS has taken the lead in carrying out this work. Other HHS agencies have also done work related to reducing antipsychotic drug use in nursing homes.

### CMS Actions

In 2012, CMS launched the National Partnership to Improve Dementia Care in Nursing Homes with federal and state agencies, nursing homes, providers, and advocacy organizations.<sup>45</sup> This was in response to several reports dating back to 2001 published by the HHS Inspector General and advocate concerns about the persistently high rate of antipsychotic drug use and quality of care provided to nursing home residents with dementia.

The National Partnership began with an initial goal of reducing the national prevalence of antipsychotic drug use in long-stay nursing home residents by at least 15 percent by December 31, 2012. CMS used publicly reported measures from the Nursing Home Compare website to

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<sup>44</sup>Alzheimer's disease is the most common type of dementia. While the National Alzheimer's Plan specifically mentions Alzheimer's disease, it also addresses related dementias.

<sup>45</sup>Throughout this document we use the term "National Partnership" to refer to the National Partnership to Improve Dementia Care in Nursing Homes.

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track the progress of the National Partnership and, according to officials, to reach out to those states and individual facilities with high prescribing rates. In the fourth quarter of 2011, which was deemed the baseline, 23.8 percent of long-stay nursing home residents nationwide were prescribed an antipsychotic drug. While the National Partnership did not reach its target reduction in 2012, by the end of 2013 the national use rate decreased to 20.2 percent, a 15.1 percent reduction.<sup>46</sup> The majority of states showed some improvements in their rates; however some states showed much more improvement than others. For example, Delaware showed a 27 percent reduction—from 21.3 to 15.5 percent—in the prevalence of antipsychotic drug use from 2011 through 2013, while Nevada saw a smaller reduction of 2.7 percent—from 20.3 to 19.7 percent—during the same period. The National Partnership is working with state coalitions, as well as nursing homes to reduce this rate even further. In September 2014, CMS established a new set of national goals to reduce the use antipsychotic drugs in long-stay nursing home residents by 25 percent by the end of 2015 and 30 percent by the end of 2016, which, assuming a baseline of 23.8 percent, would lead to a prescribing rate of 16.7 percent. Beginning in January 2015, CMS’s Five-Star Quality Rating System for nursing homes will be based, in part, on this measure of the extent to which antipsychotic drugs are used in the nursing home. The Five-Star Quality Rating System provides a way for consumers to compare nursing homes on the Medicare Web site. Previously, the measure was displayed, but not included in the calculation of each nursing home’s overall quality score.

The National Partnership works with state-based coalitions and consumer advocates to educate and promote a re-thinking of dementia care in nursing homes, with a focus on person-centered care.<sup>47</sup> In addition to state-based coalitions, the National Partnership also includes Quality Improvement Organizations (QIO), which are state-based Medicare contractors tasked with promoting the delivery of quality services to

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<sup>46</sup>The calculations CMS uses to measure antipsychotic drug use in nursing homes are somewhat different than the calculations used for the information provided in earlier sections of the report. For example, CMS’s measure is not specific to individuals with a dementia diagnosis.

<sup>47</sup>Person-centered care is an approach to care that focuses on residents as individuals and supports caregivers working most closely with them. It involves a continual process of listening, testing new approaches, and changing routines and organizational approaches in an effort to individualize and de-institutionalize the care environment.

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Medicare beneficiaries, and Advancing Excellence in America's Nursing Homes Campaign, a major initiative of the Advancing Excellence in Long Term Care Collaborative.<sup>48</sup> The National Partnership includes regular conference calls with states, regions, and advocates, and presentations by experts in the field, to share best practices and brainstorm ways to improve dementia care in their facilities.

In addition, CMS has taken four additional actions that aim to reduce antipsychotic drug use among older adults in nursing homes:

- CMS provided additional guidance and mandatory training around behavioral health and dementia care from 2012 through 2013 to the state surveyors responsible for reviewing and assessing nursing homes. This was done in order to improve surveyors' ability to identify the use of unnecessary drugs, including inappropriate use of antipsychotic drugs.
- QIOs have focused some of their efforts on reducing antipsychotic drug use in nursing homes. For example, beginning in 2013, the QIOs provided training to nearly 5,000 nursing homes on the appropriate use of antipsychotic medications.
- CMS recently concluded pilots of a new dementia-focused survey that examines the use of antipsychotic drugs to older adults with dementia living in nursing homes. CMS reported that the focused survey pilot results will allow the agency to gain new insight about the current survey process, including how the process can be streamlined to more efficiently and accurately identify and cite deficient practices as well as to recognize successful dementia care programs. The pilot consisted of onsite, targeted surveys of dementia care practices in five nursing homes in each of five states.
- CMS began reporting the rate of chronic use of atypical antipsychotic drugs by older adult Medicare beneficiaries living in nursing homes for

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<sup>48</sup>CMS is required to contract with one QIO for each of the 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. The statutory mission of the QIO is to promote the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries and to ensure that those services are reasonable and necessary. 42 U.S.C. §§ 1320c-2, 1320c-3.

The mission of the Advancing Excellence in Long Term Care Collaborative is to help nursing homes improve residents' quality of care and quality of life.

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Medicare Part D plans in 2013.<sup>49</sup> This information is publicly available on the Medicare Part D Compare Website, which is used by Medicare beneficiaries comparing Medicare Part D plans. The measure used for Medicare Part D plans differs in a few respects from the measure used to assess nursing homes. First, the Medicare Part D measure examines chronic use, defined as having at least 3 months or more of a prescription for an atypical antipsychotic drug, whereas the nursing home measure includes any use. Additionally, the Medicare Part D measure only includes atypical antipsychotic drugs, compared to the nursing home measure, which includes all antipsychotic drugs. Of the 421 Medicare Part D plans reporting in 2012, the rate of use among Medicare Part D enrollees residing in nursing homes ranged from 0 to almost 64 percent. The average among all Medicare Part D plans in 2012 was approximately 22 percent of enrollees residing in nursing homes having at least 3 months or more of a prescription. CMS told us that variation in antipsychotic prescribing among Medicare Part D plans may be explained by the prescribing practice in the plan's service area, nursing home willingness to allow the use of antipsychotic drugs for the behavioral symptoms of dementia, resident need, and success in implementing interventions to reduce the inappropriate use of antipsychotic drugs.

#### Actions of Other HHS Agencies

In addition to CMS actions, AHRQ and NIH have awarded research grants for work related to antipsychotic drug use by older adults with dementia in nursing homes.

- AHRQ has funded individual grants for work related to antipsychotic drug use in nursing homes through its Center for Evidence and Practice Improvement and the Centers for Education & Research on Therapeutics (CERT) program. For example, in 2011, CERT funded several project centers for a 5-year period to study a broad range of health care issues, including Rutgers University, which studied patterns of antipsychotic drug use, along with the safety and effectiveness of antipsychotic drug use for individuals living in nursing homes.

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<sup>49</sup>This metric specifically measures the percent of Medicare Part D beneficiaries 65 years and older who are continuously enrolled in a nursing home and who received an atypical antipsychotic medication. Medicare Part D Compare defines chronic use as any beneficiary who has received at least a 90-day supply of atypical antipsychotic medication(s) during a nursing home stay.

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- Within the NIH, the National Institute on Aging and the National Institute of Mental Health have also funded related research, including a number of studies examining the safety of antipsychotic drugs in older adults.

Some stakeholders and other provider groups we spoke with expressed overall support of HHS's efforts, while others cautioned that the emphasis should not curtail access to those individuals who need antipsychotic drugs. Specifically, stakeholders indicated that the collaboration between public and private organizations, as part of the National Partnership, along with the sharing of practices aimed at reducing antipsychotic drug use, contributed to the campaign's success. Stakeholders also mentioned that the National Partnership allowed nursing homes to pay attention and start talking about issues related to antipsychotic drug use. Some stakeholders further indicated that HHS's initiatives have brought focus to the issue of antipsychotic drug use in older adults in nursing homes. Conversely, other groups and individuals involved in HHS's efforts expressed concern that the emphasis on reducing antipsychotic drug use in nursing homes could result in some individuals who need these medications not receiving them. One researcher we spoke with noted that because nursing homes' use of antipsychotic drug use is measured and publicly reported, these facilities may be worried about their antipsychotic drug rate and focus on the bottom-line number instead of what is good for the individual. CMS officials told us that they are careful in their messaging to acknowledge that antipsychotic drugs have a useful prescribing purpose and therefore will never be totally eliminated. They are working with providers to develop a comprehensive view of what a patient potentially needs, emphasizing that using antipsychotic drugs should not be the first-line intervention.

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### HHS Has Taken Little Action to Educate and Provide Outreach to Reduce Antipsychotic Drug Use among Older Adults Residing Outside of Nursing Homes

While the National Alzheimer's Plan was established to improve care for all individuals with dementia regardless of the setting where they reside, HHS efforts related to reducing antipsychotic drug use among older adults have primarily focused on those living in nursing homes with less activity geared toward those living outside of nursing homes. HHS officials noted that the focus has been on reducing antipsychotic drug use rates in nursing homes for a variety of reasons, including the severity of dementia among nursing home residents and the agency's responsibility to ensure appropriate training of nursing home staff. However, the risk of antipsychotic drugs to older adults is not specific to those in nursing homes. Furthermore, we found that 1 in 7 Medicare Part D enrollees with

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dementia outside of the nursing home were prescribed an antipsychotic drug in 2012.

We identified one activity by HHS's ACL that examined a topic related to the use of antipsychotic drugs, specifically the use of non-pharmacological interventions in the treatment of individuals with dementia. In 2012, ACL partnered with a research group to conduct a study on non-pharmacological treatments and care practices for individuals with dementia and their caregivers.<sup>50</sup> The study results were presented in a white paper and disseminated on the ACL's Web page. ACL also included the study results in a newsletter distributed to state organizations on aging. ACL officials also told us that they participate in the National Partnership as a stakeholder organization, including reviewing the training materials that were distributed to nursing homes. However, ACL officials told us that none of their other past activities have dealt specifically with reducing antipsychotic drug use among older adults outside of nursing homes.

While ACL has not focused on reducing antipsychotic drug use among older adults outside of nursing homes, ACL is responsible for other parts of the National Alzheimer's Plan related to improving dementia care in the community. ACL partners with national groups to share information on dementia-related issues such as caring for minority populations with dementia and preventing elder abuse and neglect. As part of this work, ACL works with organizations, such as the Alliance for Aging Research and the National Family Caregiver Alliance, to share research, host webinars and presentations, and promote issues through social media. ACL also funds grants for state long-term care ombudsmen that are responsible for advocating for older adults living in nursing homes, assisted living facilities, and other residential settings for older adults.

Stakeholder groups we spoke to indicated that educational efforts similar to those provided under the National Partnership should be extended to those providing care to older adults in other settings, such as hospitals and assisted living facilities. Some stakeholders noted that some of the same material regarding non-pharmacological interventions could be shared with caregivers in these other care settings.

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<sup>50</sup>See K. Maslow, "Translating Innovation to Impact."

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Many experts we spoke with said that many nursing home residents come to the nursing home already on an antipsychotic drug. Extending educational efforts to caregivers and providers outside of the nursing home could help lower the use of antipsychotics among older adults with dementia living both inside and outside of nursing homes.

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## Conclusion

The decision to prescribe an antipsychotic drug to an older adult with dementia is dependent on a number of factors, according to experts in the field, and must take into account the possible benefits of managing behavioral symptoms associated with dementia against potential adverse health risks. In some cases, the benefits to prescribing the drugs may outweigh the risks. HHS has taken important steps to educate and inform nursing home providers and staff on the need to reduce unnecessary antipsychotic drug use and ways to incorporate non-pharmacological practices into their care to address the behavioral symptoms associated with dementia. However, similar efforts have not been directed toward caregivers of older adults living outside of nursing homes, such as those in assisted living facilities and private residences. Targeting this segment of the population is equally important given that over 1.2 million Medicare Part D enrollees living outside of nursing homes were diagnosed with dementia in 2012 and Medicare Part D pays for antipsychotic drugs prescribed to these individuals. While the extent of unnecessary prescribing of antipsychotic drugs is unknown, older adults with dementia living outside of nursing homes are also at risk of the same dangers associated with taking antipsychotics drugs as residents of nursing homes. In fact, the National Alzheimer's Project Act was not limited to the nursing home setting, but calls upon HHS to develop and implement an integrated national plan to address dementia. HHS's National Alzheimer's Plan addresses antipsychotic drug prescribing in nursing homes only, however, and HHS activities to reduce such drug use have primarily focused on older adults residing in nursing homes. Given that HHS does not specifically target its outreach and education efforts relating to antipsychotic drug use to settings other than nursing homes, older adults living outside of nursing homes, their caregivers, and their clinicians in these settings may not have access to the same resources about alternative approaches to care. By expanding its outreach and educational efforts to settings outside nursing homes, HHS may be able to help reduce any unnecessary reliance on antipsychotic drugs for the treatment of behavioral symptoms of dementia for all older adults regardless of their residential setting.

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## Recommendation for Executive Action

We recommend that the Secretary of HHS expand its outreach and educational efforts aimed at reducing antipsychotic drug use among older adults with dementia to include those residing outside of nursing homes by updating the National Alzheimer's Plan.

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## Agency Comments

We provided a draft of this report to HHS for comment. In its written response, reproduced in appendix III, HHS concurred with our recommendation, stating that the agency will support efforts to update the National Alzheimer's Plan through continued participation on the Federal National Alzheimer's Project Act Advisory Council. HHS also provided technical comments that we incorporated as appropriate.

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As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from its date. At that time, we will send copies to the Secretary of Health and Human Services. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or [iritanik@gao.gov](mailto:iritanik@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.



Katherine M. Iritani  
Director, Health Care

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# Appendix I: Scope and Methodology for Data Analyses

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This appendix describes our methodology for analyzing the 2012 prescribing of antipsychotic drugs for older adults with dementia in nursing homes and other settings, as well as for analyzing Medicare Part D plan payments for these antipsychotic drug prescriptions. It also describes our efforts to ensure the reliability of the data.

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## Analyses of Antipsychotic Drug Prescribing for Older Adults with Dementia

We used two primary data sources to examine antipsychotic drug prescribing for older adults with dementia: the Medicare Part D Prescription Drug Event (PDE) data to identify antipsychotic drug prescribing for Medicare Part D enrollees in and outside of the nursing home,<sup>1</sup> and the Long Term Care Minimum Data Set (MDS) to identify antipsychotic drug prescribing for all nursing home residents, regardless of Medicare Part D enrollment.<sup>2</sup>

## Medicare Part D Prescription Drug Event data analyses

To estimate the extent to which older adults residing inside and outside of nursing homes are prescribed antipsychotic drugs, we first analyzed 2012 PDE data for individuals with dementia.<sup>3</sup> We used the Medicare Part D PDE data because Medicare is the primary source of insurance coverage for individuals over the age of 65 and approximately 63 percent of Medicare beneficiaries were enrolled in Medicare Part D in 2012. To identify individuals living in nursing homes, we combined the PDE claims data with data from the MDS, which includes nursing home assessments for all individuals living in nursing homes, regardless of insurance coverage. We also used data from the Medicare Master Beneficiary Summary File (MBSF),<sup>4</sup> as well as the Medicare Part D Risk File to identify diagnoses, including dementia diagnoses and diagnoses for certain conditions for which the Food and Drug Administration (FDA) has approved the use of antipsychotics drugs.<sup>5</sup> We excluded from our

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<sup>1</sup>The PDE data contain pharmacy claims for all prescription drugs dispensed to Medicare Part D beneficiaries.

<sup>2</sup>The MDS contains information from nursing home resident assessments for all Medicare or Medicaid certified nursing homes, regardless of payer. In 2012, over 15,600 nursing homes were Medicare and Medicaid certified and included in the MDS.

<sup>3</sup>The 2012 PDE data were the most recent data available at the time of our review.

<sup>4</sup>MBSF includes data on enrollment, spending, and use of services for all Medicare beneficiaries.

<sup>5</sup>The Medicare Part D Risk File contains enrollee information such as age, gender, and diagnoses from the previous year.

estimates individuals with dementia also diagnosed with one of these FDA-approved conditions for antipsychotic drugs—schizophrenia and bipolar disorder. The Medicare Part D Risk File contains diagnoses based on claims from the previous year for each enrollee, so our diagnosis categories may be conservative estimates as they did not take into account longer-standing or newer diagnoses. We also excluded enrollees with outlier data, enrollees with less than 12 months of Medicare Part D enrollment in 2012, and those enrollees who died in 2012 because they did not have complete Medicare Part D data for the entire year. Finally, we excluded enrollees who resided outside of the 50 states and the District of Columbia.

For these analyses, we define an individual as having been prescribed an antipsychotic drug if they were prescribed at least one prescription for an antipsychotic drug during the year, regardless of how many days supply are covered by the prescription. We identified relevant national drug codes (NDC) using a list of generic names for antipsychotic drugs,<sup>6</sup> and, using those codes, we determined the number and percent of Medicare Part D enrollees who were prescribed an antipsychotic drug in 2012.<sup>7</sup> The specific drugs included are listed in table 6.

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<sup>6</sup>NDCs uniquely identify specific drug products for a given manufacturer.

<sup>7</sup>We did so using Red Book, a compendium published by Truven Health Analytics that includes information about the characteristics of drug products. Some included drugs have been discontinued. We excluded NDCs for drugs with a route of administration that was not oral or sublingual. We also excluded drugs that contain antipsychotics but are not classified as antipsychotic.

**Table 6: Antipsychotic Drugs Included in GAO Analysis, by Generation**

<b>First generation (conventional)</b>	<b>Second generation (atypical)</b>
Chlorpromazine Hydrochloride	Aripiprazole
Fluphenazine Hydrochloride	Asenapine
Haloperidol; Haloperidol Lactate	Clozapine
Loxapine Hydrochloride (discontinued); Loxapine Succinate	Iloperidone
Mesoridazine Besylate (discontinued)	Lurasidone Hydrochloride
Molindone Hydrochloride (discontinued)	Olanzapine
Perphenazine	Paliperidone
Pimozide	Quetiapine Fumarate
Promazine Hydrochloride (discontinued)	Risperidone
Thioridazine (discontinued); Thioridazine Hydrochloride	Ziprasidone Hydrochloride
Thiothixene; Thiothixene Hydrochloride (discontinued)	
Trifluoperazine Hydrochloride	

Source: GAO summary. | GAO-15-211

Notes: Antipsychotic drugs are classified into two sub-groups. The first generation of antipsychotic drugs, also known as “conventional” antipsychotic drugs, was developed in the mid-1950s. The second generation of antipsychotic drugs, also known as “atypical” antipsychotics, was developed in the 1980s. We excluded NDCs for drugs that are not classified as antipsychotics and do not have an oral or sublingual route of administration.

Within the nursing home population, our analysis of PDE data specifically identified those with a long stay in the nursing home—defined by the Centers for Medicare & Medicaid Services (CMS) as more than 100 days—because drugs for individuals with short stays—100 days or less—are generally covered under Medicare Part A, not Part D. We disaggregated the data to examine certain characteristics, such as gender, age, and geographic location.

Long Term Care Minimum Data Set analysis

To supplement our analysis of the Medicare Part D data for the nursing home population, we also analyzed 2012 data on antipsychotic prescribing and diagnoses among nursing home residents available in the MDS. This allowed us to look at a more comprehensive population of nursing home residents—all residents in a Medicare or Medicaid certified nursing home—and to examine prescribing rates by length of stay, using steps identified by CMS based on dates reported in the nursing home

assessments.<sup>8</sup> In addition to excluding residents with dementia also diagnosed with schizophrenia and bipolar disorder, we excluded residents with Tourette syndrome, a condition for which FDA has approved the use of certain antipsychotics, as well as Huntington's disease, a condition for which CMS guidance has recognized antipsychotics as an acceptable treatment.<sup>9</sup> Individuals with both dementia and at least one of these diagnoses accounted for about 7 percent of nursing home residents with dementia overall. We also excluded residents with outlier identification codes or other outlier data, residents under the age of 65, and residents in facilities outside of the 50 states and the District of Columbia. We included only those residents that lived through 2012 so that there was a complete year of data for each resident and because antipsychotic drugs can be used in a hospice setting to make residents more comfortable at the end of their lives.<sup>10</sup> For this analysis, we determined an individual was prescribed an antipsychotic drug if any nursing home assessment during 2012 indicated the resident took an antipsychotic drug during the previous 7 days, and we include any instance where antipsychotic use is documented.<sup>11</sup> We disaggregated the data to examine certain characteristics, such as gender, age, and geographic location.

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## Medicare Part D Plan Payments

To identify what Medicare Part D plans paid for antipsychotic drugs prescribed to older adults with dementia in 2012, we identified individuals with dementia using the Medicare Part D Risk File, and calculated plan

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<sup>8</sup>We looked at rates for those residents with a long stay, defined as more than 100 cumulative days in a facility, and a short stay, defined as all other residents.

<sup>9</sup>It was not possible to exclude other conditions on this basis such as nausea and severe depression refractory to other therapies without a medical record review. Therefore, these conditions are not included in our exclusions. In addition, we were unable to exclude Medicare Part D enrollees with Tourette syndrome and Huntington's disease for the Medicare PDE analysis because the Medicare Part D Risk File does not contain information on whether an enrollee has been diagnosed with these conditions. Of nursing home residents in 2012, approximately 0.06 percent were diagnosed with Huntington's disease and 0.02 percent were diagnosed with Tourette syndrome.

<sup>10</sup>We conducted a sensitivity analysis to determine whether the prescribing rate changed as a result of including residents who died in the facility in 2012, and the prescribing rate did not change significantly.

<sup>11</sup>This differs from the CMS measures of antipsychotic drug use among nursing home residents. For example, the CMS measure for residents that spend 100 days or less in a nursing home does not include instances of antipsychotic drug use documented on an initial assessment.

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payments for those enrollees using the PDE claims data. We also calculated plan payments for the most commonly prescribed antipsychotic drugs, and used the National Plan and Provider Enumeration System (NPPES) to identify the breakdown of prescriber specialties listed on antipsychotic drug claims under Medicare Part D in 2012 to calculate the share of plan payments for prescriptions from the specialties with the most antipsychotic prescribing for individuals with dementia.<sup>12</sup>

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## Data Reliability and Audit Standards

We ensured the reliability of the MDS data, Medicare PDE data, Medicare Part D Risk File data, MBSF data, Red Book data, and NPPES data used in this report by performing appropriate electronic data checks, reviewing relevant documentation, and interviewing officials and representatives knowledgeable about the data, where necessary. We found the data were sufficiently reliable for the purpose of our analyses.

We conducted this performance audit from January 2014 through January 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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<sup>12</sup>NPPES is a list of all Medicare providers, including unique provider identifiers, maintained by CMS.

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# Appendix II: Literature Review

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To identify what is known from published research about factors contributing to the prescribing of antipsychotic drugs to older adults with dementia, we conducted a literature search among recently published articles; specifically, we searched for relevant articles published from January 1, 2009, through March 31, 2014. We conducted a structured search of various databases for relevant peer reviewed and industry journals including MEDLINE, BIOSIS Previews, and ProQuest. Key terms included various combinations of “antipsychotic,” “dementia,” “elderly,” “older adults,” “nursing homes,” “community,” “assisted living,” “home health,” “medication management,” and “medication monitoring.” From all database sources, we identified 386 articles. We first reviewed the abstracts for each of these articles for relevancy in identifying contributing factors related to the use of antipsychotic drugs both inside and outside of nursing homes. For those articles we found relevant, we reviewed the full article and excluded those where the research (1) was conducted outside the United States; (2) included individuals less than 65 years of age; or (3) was an editorial submission. We added one article that could be linked to original research outside of the research cited in the article. After excluding these articles and including others, 42 articles remained: 22 focused on nursing homes; 11 focused on settings outside of nursing homes; 7 focused on both settings; and in 2 articles, the settings were either unclear or undetermined. Articles were then coded by analysts according to whether they identified contributing factors for use of antipsychotic drugs. We found 18 that contained detailed reasons that contribute to antipsychotic drug use among older adults:

Bowblis, J. R., S. Crystal, O. Intrator, and J. A. Lucas. “Response to Regulatory Stringency: The Case of Antipsychotic Medication Use in Nursing Homes.” *Health Economics*, vol. 21 (2012).

Briesacher, B. A., J. Tjia, T. Field, K. M. Mazor, J. L. Donovan, A. O. Kanaan, L. R. Harrold, C. A. Lemay, and J. H. Gurwitz. “Nationwide Variation in Nursing Home Antipsychotic Use, Staffing and Quality of Care.” *Abstracts of the 28<sup>th</sup> ICPE 2012*, (2012).

Briesacher, B. A., J. Tjia, T. Field, D. Peterson, and J. H. Gurwitz. “Antipsychotic use Among Nursing Home Residents.” *The Journal of American Medical Association*, vol. 309, no. 5 (2013).

Chen, Y., B. A. Briesacher, T. S. Field, J. Tjia, D. T. Lau, and J. H. Gurwitz. “Unexplained Variation across U.S. Nursing Homes in Antipsychotic Prescribing Rates.” *Archives of Internal Medicine*, vol. 170, no. 1 (2010).

Crystal, S., M. Ofison, C. Huang, H. Pincus, and T. Gerhard. "Broadened Use of Atypical Antipsychotics: Safety, Effectiveness, and Policy Challenges: Expanded Use of these Medications, Frequently Off-label, Has Often Outstripped the Evidence Base for the Diverse Range of Patients Who Are Treated with Them." *Health Affairs*, vol. 28, no. 5 (2009).

Department of Health and Human Services – Office of Inspector General, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, OEI-07-08-00150, May 2011.

Fung, V., M. Price, A. B. Busch, M. B. Landrum, B. Fireman, A. Nierenberg, W. H. Dow, R. Hui, R. Frank, J. P. Newhouse, and J. Hsu. "Adverse Clinical Events among Medicare Beneficiaries Using Antipsychotic Drugs: Linking Health Insurance Benefits and Clinical Needs." *Medical Care*, vol. 51, no. 7 (2013).

Healthcare Management Solutions, LLC and the Meyers Primary Care Institute at the University of Massachusetts Medical School. *Antipsychotic Drug Use Project Final Report* (Columbia, Md.: January 2013).

Kamble, P., J. Sherer, H. Chen, and R. Aparasu. "Off-Label Use of Second-Generation Antipsychotic Agents among Elderly Nursing Home Residents." *Psychiatric Services*, vol. 61, no. 2 (2010).

Kamble, P., H. Chen, J. T. Sherer, and R. R. Aparasu. "Use of Antipsychotics among Elderly Nursing Home Residents with Dementia in the United States: An Analysis of National Survey Data." *Drugs & Aging*, vol. 26, no. 6 (2009).

Lemay, C. A., K. M. Mazor, T. S. Field, J. Donovan, A. Kananaan, B. A. Briesacher, S. Foy, L. R. Harrold, J. H. Gurwitz, and J. Tjia. "Knowledge of and Perceived Need for Evidence-Based Education about Antipsychotic Medications among Nursing Home Leadership and Staff." *The Journal of American Medical Directors Association*, vol. 14, no. 12 (2013).

Lucas, J. A., S. Chakravarty, J. R. Bowblis, T. Gerhard, E. Kalay, E. K. Paek, and S. Crystal. "Antipsychotic Medication Use in Nursing Homes: A Proposed Measure of Quality." *International Journal of Geriatric Psychiatry* (2014).

Molinari, V. A., D. A. Chiriboga, L. G. Branch, J. Schinka, L. Shonfeld, L. Kos, W. L. Mills, J. Krok, and K. Hyer. "Reasons for Psychiatric Medication Prescription for New Nursing Home Residents." *Aging & Mental Health*, vol. 15, no.7 (2011).

Rhee, Y., J. G. Cernansky, L. L. Emanuel, C. G. Chang, and J. W. Shega. "Psychotropic Medication Burden and Factors Associated with Antipsychotic Use: An Analysis of a Population-Based Sample of Community-Dwelling Older Persons with Dementia." *The Journal of American Geriatrics Society*, no. 59 (2011).

Saad, M., M. Cassagnol, and E. Ahmed. "The Impact of FDA's Warning on the Use of Antipsychotics in Clinical Practice: A Survey." *The Consultant Pharmacist*, vol. 25, no. 11 (2010).

Sapra, M., A. Varma, R. Sethi, I. Vahia, M. Chowdhury, K. Kim, and R. Herbertson. "Utilization of Antipsychotics in Ambulatory Elderly with Dementia in an Outpatient Setting." *Federal Practitioner*, (2012).

Tjia, J., T. Field, C. Lemay, K. Mazor, M. Pandolfi, A. Spenard, S. Ho, A. Kanaan, J. Donovan, J. H. Gurwitz, and B. Briesacher. "Antipsychotic Use in Nursing Homes Varies By Psychiatric Consultant." *Medical Care*, vol. 52, no. 3. (2014).

Watson-Wolfe, K., E. Galik, J. Klinedinst, and N. Brandt. "Application of the Antipsychotic Use in Dementia Assessment Audit Tool to Facilitate Appropriate Antipsychotic Use in Long Term Care Residents with Dementia." *Geriatric Nursing*, vol. 35 (2014).

# Appendix III: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

Katherine Iritani  
Director, Health Care  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

Dear Ms. Iritani:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Antipsychotic Drug Use: HHS Has Initiatives to Reduce Use among Older Adults in Nursing Homes, but Should Expand Efforts to Other Settings" (GAO-15-211).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in black ink that reads "Jim R. Esquea".

Jim R. Esquea  
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: ANTIPSYCHOTIC DRUG USE: HHS HAS INITIATIVES TO REDUCE USE AMONG OLDER ADULTS IN NURSING HOMES, BUT SHOULD EXPAND EFFORTS TO OTHER SETTINGS (GAO-15-211)**

The U.S. Department of Health and Human Services (HHS) appreciates the Government Accountability Office (GAO) for the opportunity to review and comment on this draft report.

**GAO Recommendation**

GAO recommends that the Secretary of HHS expand its outreach and educational efforts aimed at reducing antipsychotic drug use among older adults with dementia residing outside of nursing homes by updating the National Alzheimer's Plan.

**HHS Response**

HHS concurs with this recommendation. HHS will support efforts to update the National Alzheimer's Plan through continued participation on the Federal National Alzheimer's Project Act Advisory Council.

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# Appendix IV: GAO Contact and Staff Acknowledgments

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## GAO Contact

Katherine M. Iritani, (202) 512-7114 or [iritanik@gao.gov](mailto:iritanik@gao.gov)

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## Staff Acknowledgments

In addition to the contact named above, Lori Achman, Assistant Director; Todd D. Anderson; Shaunessye D. Curry; Leia Dickerson; Sandra George; Kate Nast Jones; Ashley Nurhussein-Patterson; and Laurie Pachter made key contributions to this report.

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## Public Affairs

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