Antipsychotic Use in Part D Enrollees with Dementia

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Background

CMS has been particularly concerned with the unnecessary use of antipsychotic drugs in nursing homes and, as a result, has pursued strategies to increase awareness of antipsychotic use in long term care. In 2013, we began to calculate a general atypical antipsychotic utilization rate, called *Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes*, for inclusion in the 2013 Part D display measures using 2011 data. The average rates decreased from approximately 24.0% in 2011 to 19.4% in 2014.

There continues to be increased attention on this important issue. The United States Government Accountability Office (GAO) released a report[1] in January 2015 describing the inappropriate use of antipsychotics in Part D beneficiaries with dementia, in both community (i.e., outside of nursing homes) and long-stay nursing home residents during 2012, with recommendations for CMS to address this problem. The GAO conducted this study due to concerns raised regarding the use of antipsychotic drugs to address the behavioral symptoms associated with dementia, the FDA's boxed warning that these drugs may cause an increased risk of death when used by older adults with dementia, and the fact that antipsychotic drugs are not approved for this use.

In addition, the Pharmacy Quality Alliance (PQA) endorsed a new measure, *Antipsychotic Use in Persons with Dementia (APD).* This provides CMS with a new measure developed through a consensus process to monitor the inappropriate use of antipsychotics in both the nursing home and community settings across Medicare Part D plans.

Objectives

The objectives of our analyses are to:

1. Verify the GAO's findings using a comparable methodology.
2. Test and develop a new Part D measure based on the PQA measure, *Antipsychotic Use in Persons with Dementia*, with breakouts by nursing home and community settings, and summarize the findings to potentially add to the Part D display measure set.

1. Verification of GAO's Findings

The GAO reported that approximately 33 percent of older adult Medicare Part D enrollees with dementia who spent more than 100 days in a nursing home (defined as long-stay nursing home residents) in 2012 were prescribed an antipsychotic. Among Medicare Part D enrollees with dementia who spent no time in a nursing home (community-only residents) that same year, about 14 percent were prescribed an antipsychotic. GAO's analysis of MDS data, regardless of enrollment in Part D, showed that approximately 30 percent of all older adult nursing home residents with a dementia diagnosis were prescribed an antipsychotic drug at some point during their 2012 nursing home stay; 23% for short-stay residents and 33% for long-stay residents.

[1] Antipsychotic Drug Use: HHS Has Initiatives to Reduce Use among Older Adults in Nursing Homes, but Should Expand Efforts to Other Settings. http://www.gao.gov/products/*GAO-15-211*. *GAO-15-211*: Published: Jan 30, 2015. Publicly Released: Mar 2, 2015

The GAO's report methodology was as follows:

- To identify individuals living in nursing homes, Medicare Part D Prescription Drug Event (PDE) data were combined with 2012 data from the Long Term Care Minimum Data Set (MDS), which includes nursing home assessments for all individuals living in nursing homes, regardless of insurance coverage.
- Data from the Medicare Master Beneficiary Summary File (MBSF) and the Medicare Part D Risk (RAPS) file were used to identify diagnoses, including dementia and mental health diagnoses for which FDA has approved the use of antipsychotic drugs.
- Only those beneficiaries that survived through 2012 were included in order to exclude patients who received antipsychotics within hospice or palliative settings at the end of life.
- Individuals with dementia also diagnosed with schizophrenia and bipolar disorder, which are FDA-approved conditions for antipsychotic drugs, were excluded.
- An individual was counted as an antipsychotic user if he/she was prescribed at least one prescription for an antipsychotic drug during the year, regardless of the days supply of the prescription.
- The nursing home population was limited to beneficiaries with a long stay (i.e., more than 100 days; Part A often covers prescriptions dispensed during stays less than 100 days) and Part D prescription coverage.
- Antipsychotic prescription fills were identified in the PDE data using the relevant national drug codes (NDCs) for antipsychotic drugs. NDCs were identified using the Red Book drug database.

We approximated the findings of the 2015 GAO report on antipsychotic use in Part D patients with dementia during 2012 with support from our contractor, Acumen LLC, by replicating the methods described in the report as closely as possible. While some of the exact data sources and specifications used by GAO are not available in the report, this analysis used multiple iterations of the same metrics based on different data sources for identifying diagnoses to provide several points of comparison. This is described in more detail below.

Measure Specifications and Data Sources

To parallel GAO's analysis, our analysis excludes beneficiaries who:

- were younger than 65 (defined as those under the age of 65 as of 1/1/2012)
- had a dementia diagnosis and an exclusion diagnosis (Schizophrenia, Bipolar Disorders, Huntington's disease, Tourette syndrome)[2]
- were enrolled in Part D for less than 12 months in 2012 (Part D enrollment limited to E, H, R, and S contracts)
- had a death date in 2012
- ever resided outside of the 50 states and D.C. in 2012

[2] Huntington's disease and Tourette syndrome diagnoses are not available in the RAPS file, but are available in the CWF and MDS data. The GAO analysis may not exclude beneficiaries with these diagnoses if based only on the RAPS data.

The GAO analysis additionally excludes beneficiaries who:

- did not have Medicare coverage prior to 1/1/2011
- had outlier data identification codes or other outlier data

This analysis does not apply these restrictions.

This analysis used the following specifications for the rate calculation:

> **Denominator:** All beneficiaries 65 and older with (i) a dementia diagnosis and (ii) no diagnosis of Schizophrenia, Bipolar Disorders, Huntington's disease, or Tourette syndrome.
>
> **Numerator:** All beneficiaries in the denominator population with at least one prescription for any antipsychotic medication with a date of service in 2012 (regardless of days supply).

Table 1 compares the sources used by GAO and CMS for NDCs, drug claims, enrollment, diagnosis, and nursing home enrollment for year-of-service (YOS) 2012.

Table 1: Data Source Comparison

Data Element	GAO	CMS
Drugs (NDC)	Red Book	Medi-Span/First DataBank
Drug claims	Prescription Drug Event (PDE) Data	
Diagnoses	Risk Adjustment Processing System (RAPS, Part D Risk File)	
	Master Beneficiary Summary File (MBSF)* Minimum Data Set (MDS)	Common Working File (CWF) Inpatient (IP), Outpatient (OP), Carrier claims
Nursing Home Enrollment	Minimum Data Set (MDS)	
Medicare Enrollment	Master Beneficiary Summary File (MBSF)	Common Medicare Environment (CME)

* The MBSF uses the Chronic Condition Warehouse (CCW) as the source of diagnosis data. Managed care encounter data is not available in CCW for people enrolled in Medicare Advantage (MA) plans. Similarly, the CWF does not include outpatient or carrier claims for MA-PDs.

Table 2 lists the sources for diagnosis information used for each iteration performed for both dementia and the mental health diagnoses, and the differences between these sources. All iterations provided findings similar to the GAO's; however, the Full CWF + RAPS diagnosis definition analysis best approximated the GAO findings. Therefore, we selected the Full CWF + RAPS diagnoses sources for our final analysis.

Table 2. Multiple CMS Iterations: Diagnosis definition data source(s):

Data Source	Diagnoses Included	Comments
1. RAPS Only	Prescription Drug Hierarchical Condition Categories (RxHCCs) include prior year diagnoses only	Available for all contracts, diagnoses are based on prior year (i.e., 2013 RxHCCs based on 2012 diagnoses). RAPS data is updated in late summer based on diagnoses from the prior year.
2. Full CWF + RAPS	Current year IP, OP, Carrier claims + prior year RxHCCs	Same as above, OP and Carrier claims available for PDP contracts only.
3. Full CWF + RAPS + MDS	Current year IP, OP, Carrier claims + prior year RxHCCs + MDS diagnoses	Same as above, MDS diagnosis included if diagnosis ever present in an assessment during the year.

Our analysis used the ICD-9 diagnoses codes (DGNs), RxHCCs, and MDS codes summarized in Table 3 to identify beneficiaries with the conditions of interest. Specific diagnosis codes used in the GAO analysis were not available in the report.

Table 3: Diagnosis Codes Included in Analysis

Disease Diagnoses	CMS Diagnoses		
	ICD-9 Codes (per PQA specifications)	RxHCC Codes (per GAO Report)	MDS Codes (per GAO Report)
Dementia Diagnoses			
Alzheimer's Disease	331	54	I4200_ALZHMR_CD
Dementia, Except Alzheimer's Disease	290, 290.1x, 290.3, 290.4x, 294.1, 294.2	55	I4800_DMNT_CD
Parkinson's Disease	331.82	76	I5300_PRKNSN_CD
Exclusion Diagnoses			
Schizophrenia	295.0x to 295.9x	58	I6000_SCHZOPRNIA_CD
Bipolar Disorders	296.0x, 296.1x, 296.4x to 296.9x	59	I5900_MNC_DPRSN
Huntington's Disease	333.4	Not Available	I5250_HNTGTN_CD
Tourette Syndrome	307.23	Not Available	I5350_TOURT_CD

We created an NDC list based on the products specified in the GAO report. These products are included in Table 4.

Table 4: Drug Product List

GAO Product List	
First generation (conventional)	**Second Generation (atypical)**
Chlorpromazine Hydrochloride	Aripiprazole
Fluphenazine Hydrochloride	Asenapine
Haloperidol; Haloperidol Lactate	Clozapine
Loxapine Hydrochloride*; Loxapine Succinate	Iloperidone
Mesoridazine Besylate*	Lurasidone Hydrochloride
Molindone Hydrochloride*	Olanzapine
Perphenazine	Paliperidone
Pimozide	Quetiapine Fumarate
Promazine Hydrochloride*	Risperidone
Thioridazine*; Thioridazine Hydrochloride	Ziprasidone Hydrochloride
Thiothixene; Thiothixene Hydrochloride*	
Trifluoperazine Hydrochloride	

*GAO reported that some of the included drugs from the Red Book have been discontinued, which may limit the drug claims for these products.

GAO's analysis excluded NDCs with routes of administration other than oral or sublingual and NDCs that contain antipsychotic drugs but are not classified as antipsychotics according to the Red Book data source. Our analysis did not apply these additional exclusions.

Nursing Home Stay Definitions

Both the GAO and CMS analyses assessed antipsychotic use in persons with dementia across different settings, using the MDS data to identify nursing home residents.

- A beneficiary was considered a long-stay nursing home resident if he/she had a stay greater than 100 cumulative days in a nursing home during the year.
- Beneficiaries who spent less than or equal to 100 cumulative days in a nursing home were considered short-stay nursing residents.
- Beneficiaries with zero days in a nursing home were defined as community-only residents.

Each beneficiary was counted in only one category for the entire measurement period within a contract and not considered separately for time spent in different settings (e.g., a beneficiary who experienced both short-term and long-term nursing home stays was included only in the long-term APD rate).

Key Findings

Overall, our analysis findings were similar to the GAO's study and demonstrated similar trends. Both studies reported the same overall Medicare Part D APD rates for long-stay nursing home beneficiaries (33%, Table 5 below) and similar rates for community-only residents (14% vs. 15%, Table 6 below).

GAO did not report a Medicare Part D APD rate for short-term nursing home stays because Part A often covers prescriptions during short-term nursing home stays. However, GAO's analysis of MDS data, regardless of enrollment in Part D, showed that approximately 23% of short-stay nursing home residents with a dementia diagnosis were prescribed an antipsychotic drug at some point during their 2012 nursing home stay. Although we did not attempt to replicate GAO's findings for all nursing home residents regardless of Part D coverage, our analysis demonstrated a short-term Medicare Part D APD rate of 21%.

The key difference between the GAO analysis and ours is that we identified more beneficiaries with dementia as nursing home residents, and the GAO identified more as community-only residents. The GAO identified 24% more beneficiaries in the community-only setting while the number of beneficiaries identified with dementia and receiving an antipsychotic was only 11% higher. Therefore, our community APD rates were slightly higher (one percentage point) than the GAO's, overall and by resident characteristics. However, the stratified nursing home resident population rates were the same in both analyses for most population characteristics. Stratified analysis found the following population rate differences:

- APD rates were 4-5 percentage points higher for males compared to female nursing home residents; on the other hand, in community-only residents, the APD rates for males were 3 percentage points lower compared to females.
- APD rates decreased as age increased within the nursing home population. This trend was reversed in the community-only setting and the rates were slightly higher in the CMS analysis compared to the GAO report.
- The south region had the highest APD rates across all settings, with the greatest percentage point difference found among long-term nursing home residents in the south region compared to other locations.

Table 5: GAO and CMS Comparable Results, Long-Term Nursing Home Residents

Part D Beneficiaries with Dementia		GAO Long-Term Nursing Home Residents*			CMS Long-Term Nursing Home Residents**		
		Number without antipsychotic prescription	Number with antipsychotic prescription	Percent with antipsychotic prescription	Number without antipsychotic prescription	Number with antipsychotic prescription	Percent with antipsychotic prescription
Total		**268,486**	**131,480**	**33%**	**283,776**	**140,705**	**33%**
Gender	Female	206,215	95,911	32%	218,311	102,950	32%
	Male	62,271	35,569	36%	65,465	37,755	37%
Age	66-74	28,888	19,842	41%	32,004	21,936	41%
	75-84	89,131	51,014	36%	95,189	54,509	36%
	85+	150,467	60,624	29%	156,583	64,260	29%
Census Location	Midwest	73,906	33,743	31%	78,368	36,431	32%
	Northeast	68,648	31,120	31%	70,879	32,591	31%
	South	93,026	52,938	36%	100,095	57,288	36%
	West	32,906	13,679	29%	34,434	14,395	29%

***** Diagnosis data sources: RAPS, MBSF, and MDS

******Diagnosis data sources: Full CWF and RAPS

Table 6: GAO and CMS Comparable Results, Community-Only Population, 2012

Part D Beneficiaries with Dementia		GAO Community Only*			CMS Community Only**		
		Number without antipsychotic prescription	Number with antipsychotic prescription	Percent with antipsychotic prescription	Number without antipsychotic prescription	Number with antipsychotic prescription	Percent with antipsychotic prescription
Total		**1,056,433**	**170,286**	**14%**	**851,101**	**153,805**	**15%**
Gender	Female	677,304	119,779	15%	541,163	106,840	16%
	Male	379,129	50,507	12%	309,938	46,965	13%
Age	66-74	238,542	33,328	12%	195,861	32,016	14%
	75-84	468,323	73,171	14%	382,977	66,389	15%
	85+	349,568	63,787	15%	272,263	55,400	17%
Census Location	Midwest	225,473	30,913	12%	179,532	26,833	13%
	Northeast	204,389	34,316	14%	162,375	29,634	15%
	South	384,800	65,196	15%	324,623	62,202	16%
	West	241,771	39,861	14%	184,571	35,136	16%

***** Diagnosis data sources: RAPS, MBSF, and MDS

******Diagnosis data sources: Full CWF and RAPS

Conclusion

Although the actual number of beneficiaries identified as long-term nursing home and community-only residents between the GAO and our study were different, the proportions of beneficiaries with dementia receiving an antipsychotic without an FDA-approved indication were either the same for long-term nursing home residents (33%) or slightly different for community only residents (GAO, 14% vs. CMS, 15%). Our study confirms the GAO's findings.

The differences in CMS and GAO findings are likely due to methodological choices that we made when trying to match GAO's specifications:

- Sources of enrollment information and application of population restrictions: The GAO used MBSF and we used the CME for enrollment data. The GAO analysis excluded beneficiaries who

did not have Medicare coverage prior to 1/1/2011 or had outlier data identification codes or other outlier data. Our analysis did not apply these restrictions.

- Sources of diagnoses data: The GAO analysis used RAPS data, MBSF, and MDS codes to identify diagnoses, whereas our analysis used RAPS data and ICD-9 Codes available in the CWF. Huntington's disease and Tourette syndrome diagnoses are not available in the RAPS file, but are available in the CWF and MDS data. The GAO analysis may not have excluded beneficiaries with these diagnoses if based only on the RAPS data. This would have the greatest impact in the analysis of the community-only population; GAO used MDS data to supplement the diagnoses of nursing home residents. GAO also states that, as a result of using the Medicare Part D Risk File, their "diagnosis categories may be conservative estimates as they did not take into account longer-standing or newer diagnoses."[3]
- Antipsychotic drug lists: GAO's analysis excluded NDCs with routes of administration other than oral or sublingual and NDCs that contain antipsychotic drugs but are not classified as antipsychotics according to the Red Book data source. Our analysis did not apply these additional exclusions and used Medi-Span and First DataBank for drug data.

2. Test and develop a new Part D measure based on the PQA measure, Antipsychotic Use in Persons with Dementia

The PQA endorsed a new measure, *Antipsychotic Use in Persons with Dementia (APD).* We tested this measure based on the PQA specifications. In addition, given the different data sources available to CMS, we investigated alternative sources of diagnosis data and various definitions of nursing home stays. We also adjusted rates based on the number of months beneficiaries are enrolled in each Part D contract (i.e., the member-years adjustment).

Measure Specifications and Data Sources

The PQA APD measure specifications that we tested differed from the GAO's as described below:

- The GAO included any prescription for an antipsychotic; whereas we required at least one antipsychotic prescription and that the beneficiary received a total day's supply of greater than 30 days.
- The GAO used RAPS data from the Medicare Part D Risk File and the MBSF to identify diagnoses within the community-only population plus the addition of MDS diagnosis data for nursing home residents, whereas we used current diagnoses data from the CWF File supplemented with RAPS data, and PDE data to identify beneficiaries actively treated for dementia.
- The GAO analyzed antipsychotic use in 2012 and our development of an APD measure used YOS 2013 data.

[3] *http://www.gao.gov/products/GAO-15-211*. P. 35.

All rate calculations use the following specifications from the PQA APD measure:

> **Denominator:** All beneficiaries 65 and older with either (i) a dementia diagnosis and/or (ii) two or more prescription claims for a dementia drug (cholinesterase inhibitor or NMDA receptor antagonist) and a total day's supply greater than 60 days.
>
> **Numerator:** All beneficiaries in the denominator population with (i) at least one antipsychotic medication prescription and a total day's supply greater than 30 days and (ii) no diagnosis of schizophrenia, bipolar disorder, Huntington's disease, or Tourette syndrome.

The APD measure rate was calculated for all contracts, MA-PDs, PDPs, and at the individual contract-level for all beneficiaries, community-only residents (never a nursing home resident), and both short-term and long-term nursing home stay residents during 2013 that meet the inclusion and exclusion criteria. We also reported the measure at each level by low-income subsidy (LIS) status (Yes or No).

This analysis used the following sources for claims, enrollment, diagnosis, and nursing home residency data from YOS 2013:

- PDE Claims
- CME
- CWF
- RAPS
- MDS

Diagnoses Data

The first step in this analysis was a comparison of methods for identifying the numerator and denominator populations, using four different combinations of diagnosis data obtained from IP, OP, and carrier claims from the CWF and RxHCCs from the RAPS. Table 7 below summarizes these definitions.

Table 7: Data Sources for Diagnosis Information

Data Source	Diagnoses Included	Comments
Partial CWF - IP Only	Current year IP claims only	Available for both MA-PD and PDP contracts.
Full CWF	Current year IP, OP, Carrier claims	OP and Carrier claims available for PDP contracts only.
RAPS Only	RxHCCs include prior year diagnoses only	Available for all contracts, diagnoses are based on prior year (i.e., 2013 RxHCCs based on 2012 diagnoses). RAPS data is updated in late summer based on diagnoses from the prior year.
Full CWF + RAPS	Current year IP, OP, Carrier claims + prior year RxHCCs	OP and Carrier claims available for PDP contracts only.

The choice of diagnosis source(s) had a significant impact on the APD rates; aggregate APD rates decreased as additional diagnoses sources were added. The additional data sources provided added opportunities to identify the diagnoses of interest, particularly the exclusion diagnoses. To provide the most current diagnoses data available, the full CWF plus RAPS data sources were selected, which resulted in APD rates approximately 30% lower than using solely inpatient data from the CWF. We expect the use of updated RAPS data in late summer when calculating the measure rates for the prior year should account for missing outpatient or carrier claim diagnoses that are not captured in the CWF for MA-PDs.

Table 8 lists the specific ICD-9 DGNs for the combined full CWF and RAPS' RxHCCs used to identify beneficiaries with the conditions of interest.

Table 8: Diagnosis Codes Included in Analysis

Disease Diagnoses	ICD-9 Codes (per PQA specifications)	RxHCC Codes
Denominator Diagnoses (Inclusion)		
Alzheimer's Disease	331	54
Dementia, Except Alzheimer's Disease	290, 290.1x, 290.3, 290.4x, 294.1, 294.2	55
Parkinson's Disease	331.82	76
Numerator Diagnoses (Exclusion)		
Schizophrenia	295.0x to 295.9x	58
Bipolar Disorders	296.0x, 296.1x, 296.4x to 296.9x	59
Huntington's Disease	333.4	Not Available
Tourette Syndrome	307.23	Not Available

PQA provided the list of drug products used in this analysis (Table 9).

Table 9: Dementia and Antipsychotic Medications

Cholinesterase Inhibitor Medications and NMDA receptor antagonists		
• donepezil • rivastigmine	• galantamine • memantine	
Antipsychotic Medications		
• Aripiprazole • Asenapine • Chlorpromazine • Clozapine • Fluphenazine • Haloperidol	• Iloperidone • Loxapine • Lurasidone • Olanzapine • Paliperidone • Perphenazine	• Pimozide • Quetiapine • Risperidone • Thioridazine • Thiothixene • Trifluoperazine • Ziprasidone

Nursing Home Stay Definitions

The second step in this analysis was to investigate multiple definitions of long-term institutional (nursing home) stays based on the LTC MDS. Table 10 summarizes two nursing home stay definitions included in the analysis.

- The Long-Term Institutional (LTI) flag, used in the current atypical antipsychotic Part D display measure, is an existing indicator provided in the yearly RAPS data, based on MDS assessments.
- The MDS Cumulative >100 indicator is based on the specifications provided in the PQA *Antipsychotic Use in Persons with Dementia using MDS Data* measure and also constructed directly from the MDS data. The MDS Cumulative >100 indicator is also consistent with CMS definitions in other measures. Beneficiaries found in the MDS but who did not have greater than 100 cumulative MDS days were classified as nursing home short-stays.

Table 10: Nursing Home Stay Definitions

Indicator	Definition of LTC Stay	Unit of Observation	Availability
RAPS LTI	>=90 days; Stay terminated after >14 days in Community	Month	Yearly
MDS Cumulative >100	> 100 cumulative MDS days	Day	Monthly

A positive indicator for either definition identifies beneficiaries as nursing home residents with long-term stays. We determined that generating the MDS indicator directly from the MDS data is a viable alternative to using the RAPS LTI indicator. The MDS' daily indicator is more precise than the RAPS monthly indicator and is available on a monthly basis while the RAPS LTI data is available only annually. Using the MDS Cumulative >100 criteria leverages these advantages, provides a large denominator file, and maintains consistency with the PQA *Antipsychotic Use in Persons with Dementia - MDS Data* measure and prior CMS definitions of long- and short-term nursing home stays.

For the final rate calculations, beneficiaries were assigned to different settings as defined below. Each beneficiary was counted in only one category for the entire measurement period within a contract, not considered separately for time spent in different settings (e.g., a beneficiary who experienced both short-term and long-term nursing home stays was included only in the long-term APD rate).

- A beneficiary was considered a long-stay nursing home resident if he/she had a stay greater than 100 cumulative days in a nursing home during the year.
- Beneficiaries who spent less than or equal to 100 cumulative days in a nursing home were considered short-stay nursing residents.
- Beneficiaries with zero days in a nursing home were defined as community-only residents.

Key Findings

APD rates across all 2013 contracts, using full CWF diagnosis plus RAPS data and the MDS Cumulative >100 nursing home stay definition, and applying the member-years adjustment, appear in Table 11. The overall APD rate was 13.23%. For community-only residents, the APD rate was 10.5%. The APD rates for short- and long-term stay nursing home residents were overall about 13.6% and 20.9%, respectively.

Although the APD rates for MA-PDs and PDPs differ, a direct comparison is not appropriate given the lack of outpatient and carrier claims in the CWF to identify diagnoses within the MA-PD population. Part A coverage of medications for some beneficiaries during short-term nursing home stays may affect APD rates for short-term nursing home stays.

Table 11. Antipsychotic Use in Beneficiaries Age 65 or Older with Dementia during 2013

Contract Type	Overall APD Rate	Community Only APD Rate (Never Nursing Home)	Short Term NH APD Rate (Cumulative MDS ≤100 Days)	Long Term NH APD Rate (Cumulative MDS >100)
ALL	13.2%	10.5%	13.5%	20.9%
MA-PD	12.2%	10.3%	14.6%	22.1%
PDP	13.6%	10.6%	13.1%	20.7%

We also prepared contract-level breakouts of the APD measure rates for all beneficiaries, community-only beneficiaries, and short- and long-term stay nursing home resident for YOS 2013, but did not include the contract-level rates in this report. Frequency distributions and statistics for the APD measure contract-level rates are presented in Tables 12 and 13.

APD rates by low-income subsidy (LIS) status are available in Table 14. Beneficiaries with LIS status have a higher overall APD rate (15.8%) than non-LIS beneficiaries (11.3%).

Table 12. Antipsychotic Use in Beneficiaries Age 65 or Older with Dementia during 2013, Frequency Distributions and Statistics of Contract-Level APD Rates*

ALL BENEFICIARIES		
Range	*Frequency*	*Cumulative %*
≤5%	33	4.5%
>5-10%	157	26.0%
>10-15%	382	78.2%
>15-20%	97	91.5%
>20-25%	33	96.0%
>25-30%	17	98.4%
>30-35%	5	99.0%
>35-40%	3	99.5%
>40-45%	2	99.7%
>45-50%	2	100.0%
>50-55%	0	100.0%
>55-60%	0	100.0%
>60-65%	0	100.0%
>65-70%	0	100.0%
>70-75%	0	100.0%
>75-80%	0	100.0%
>80-85%	0	100.0%
>85-90%	0	100.0%
>90-95%	0	100.0%
>95-100%	0	100.0%
More	0	100.0%
Descriptive Statistics (%)		
Mean	12.8%	
Standard Error	0.2%	
Median	12.1%	
Mode	0.0%	
Standard Deviation	5.8%	
Range	47.9%	
Minimum	0.0%	
Maximum	47.9%	
Sum	93.76	
Count	731	

COMMUNITY ONLY		
Range	*Frequency*	*Cumulative %*
≤5%	65	8.9%
>5-10%	324	53.2%
>10-15%	231	84.8%
>15-20%	57	92.6%
>20-25%	27	96.3%
>25-30%	15	98.4%
>30-35%	7	99.3%
>35-40%	2	99.6%
>40-45%	1	99.7%
>45-50%	2	100.0%
>50-55%	0	100.0%
>55-60%	0	100.0%
>60-65%	0	100.0%
>65-70%	0	100.0%
>70-75%	0	100.0%
>75-80%	0	100.0%
>80-85%	0	100.0%
>85-90%	0	100.0%
>90-95%	0	100.0%
>95-100%	0	100.0%
More	0	100.0%
Descriptive Statistics		
Mean	10.8%	
Standard Error	0.2%	
Median	9.7%	
Mode	0.0%	
Standard Deviation	6.2%	
Range	49.0%	
Minimum	0.0%	
Maximum	49.0%	
Sum	78.97	
Count	731	

Short-Term NH Stay		
Range	*Frequency*	*Cumulative %*
≤5%	79	11.1%
>5-10%	75	21.7%
>10-15%	286	61.9%
>15-20%	162	84.7%
>20-25%	43	90.7%
>25-30%	23	94.0%
>30-35%	14	95.9%
>35-40%	11	97.5%
>40-45%	3	97.9%
>45-50%	8	99.0%
>50-55%	3	99.4%
>55-60%	0	99.4%
>60-65%	1	99.6%
>65-70%	1	99.7%
>70-75%	0	99.7%
>75-80%	0	99.7%
>80-85%	0	99.7%
>85-90%	1	99.9%
>90-95%	0	99.9%
>95-100%	1	100.0%
More	0	100.0%
Descriptive Statistics		
Mean	14.8%	
Standard Error	0.4%	
Median	13.7%	
Mode	0.0%	
Standard Deviation	9.9%	
Range	100.0%	
Minimum	0.0%	
Maximum	100.0%	
Sum	105.34	
Count	711	

Long-Term NH Stay		
Range	*Frequency*	*Cumulative %*
≤5%	54	8.0%
>5-10%	11	9.6%
>10-15%	42	15.8%
>15-20%	119	33.3%
>20-25%	182	60.2%
>25-30%	135	80.1%
>30-35%	59	88.8%
>35-40%	27	92.8%
>40-45%	19	95.6%
>45-50%	12	97.3%
>50-55%	6	98.2%
>55-60%	2	98.5%
>60-65%	0	98.5%
>65-70%	1	98.7%
>70-75%	0	98.7%
>75-80%	1	98.8%
>80-85%	0	98.8%
>85-90%	0	98.8%
>90-95%	0	98.8%
>95-100%	8	100.0%
More	0	100.0%
Descriptive Statistics		
Mean	23.9%	
Standard Error	0.5%	
Median	22.8%	
Mode	0.0%	
Standard Deviation	13.7%	
Range	100.0%	
Minimum	0.0%	
Maximum	100.0%	
Sum	161.95	
Count	678	

* Contract counts differ because those with zero in the APD denominator are excluded.

Table 13. YOS 2013 Percentile Distribution of APD Rates among Contracts, All Beneficiaries Age 65 or Older

Rate (Includes Contracts w/ missing rate)	Organization Type	# of Contracts	Mean	Std. Dev	Min	Percentile									Max
						10th	20th	30th	40th	50th	60th	70th	80th	90th	
All Beneficiaries (13.2% overall)	**ALL**	**731**	**12.8%**	**5.8%**	**0.0%**	**7.7%**	**9.3%**	**10.3%**	**11.3%**	**12.1%**	**13.0%**	**14.0%**	**15.4%**	**19.4%**	**47.9%**
	MA-PD	652	12.8%	6.1%	0.0%	7.6%	9.1%	10.1%	10.9%	11.8%	12.7%	13.9%	15.6%	19.9%	47.9%
	PDP	79	13.1%	2.8%	0.0%	10.7%	11.6%	12.3%	12.9%	13.3%	13.9%	14.5%	15.0%	16.0%	18.8%
Community Only (10.5% overall)	**ALL**	**731**	**10.8%**	**6.2%**	**0.0%**	**5.3%**	**7.2%**	**8.1%**	**8.9%**	**9.7%**	**10.6%**	**11.7%**	**13.6%**	**17.5%**	**49.0%**
	MA-PD	652	10.8%	6.5%	0.0%	5.1%	7.0%	7.9%	8.6%	9.5%	10.5%	11.6%	13.8%	18.3%	49.0%
	PDP	79	11.1%	2.9%	0.0%	8.7%	9.4%	9.8%	10.3%	11.0%	11.4%	11.9%	12.5%	14.7%	20.3%
Short Term Nursing Home Stay (Cumulative MDS =<100 Days) (13.5% overall)	**ALL**	**711**	**14.8%**	**9.9%**	**0.0%**	**4.0%**	**9.6%**	**11.7%**	**12.9%**	**13.7%**	**14.8%**	**16.1%**	**18.3%**	**24.5%**	**100.0%**
	MA-PD	633	15.0%	10.3%	0.0%	3.1%	9.5%	11.5%	12.9%	13.8%	15.0%	16.5%	18.9%	25.3%	100.0%
	PDP	78	13.0%	5.8%	0.0%	5.7%	11.0%	12.2%	12.9%	13.2%	13.7%	14.3%	15.2%	16.5%	39.7%
Long Term Nursing Home Stay (Cumulative MDS >100) (20.9% overall)	**ALL**	**678**	**23.9%**	**13.7%**	**0.0%**	**10.6%**	**16.7%**	**19.3%**	**21.1%**	**22.8%**	**25.0%**	**27.3%**	**30.0%**	**36.0%**	**100.0%**
	MA-PD	602	24.3%	14.2%	0.0%	10.2%	16.4%	19.2%	21.5%	23.4%	25.7%	27.9%	30.7%	36.8%	100.0%
	PDP	76	20.9%	8.6%	0.0%	12.6%	17.5%	19.8%	20.6%	21.0%	21.5%	22.4%	23.9%	26.3%	59.5%

Table 14: Distribution of Contract APD Rates by Low-Income Subsidy (LIS) Status

	# of Contracts	Mean	Std. Dev.	Min	Percentiles									Max
					10th	20th	30th	40th	50th	60th	70th	80th	90th	
All	**731**	**12.8%**	**5.8%**	**0.0%**	**7.7%**	**9.3%**	**10.3%**	**11.3%**	**12.1%**	**13.0%**	**14.0%**	**15.4%**	**19.4%**	**47.9%**
LIS	726	15.8%	7.4%	0.0%	7.8%	10.6%	12.6%	14.3%	15.6%	17.2%	18.7%	20.6%	23.8%	71.4%
Non-LIS	630	11.3%	12.3%	0.0%	0.0%	6.9%	8.1%	8.9%	9.7%	10.4%	11.4%	12.6%	15.0%	100.0%

The rates presented in Tables 11 to 14 do not exclude outliers, which are often due to contracts with very small denominators in their rate calculations. If these rates were presented as Part D display measures or Star Ratings measures, the APD rates would be limited to contracts with greater than 30 beneficiary-years in the denominator. The number of contracts that would be excluded for each population ranges from 66 to 270 contracts (see Table 15). The removal of outlier rates due to low denominators would change the overall APD rate for each population.

Table 15: APD Rates of Contracts with 30+ Beneficiary-years in Denominator

	Contracts		APD Rate		
Population	**Exclude**	**Include**	**Average**	**Minimum**	**Max**
All Beneficiaries	66	665	12.6%	0.0%	38.3%
Community-only	86	645	10.4%	0.0%	32.9%
Short-term NH Stay	223	488	13.7%	2.2%	50.0%
Long-term NH Stay	270	408	22.8%	4.9%	43.8%

Conclusion

We recommend developing 2016 new patient safety APD measure reports to provide to Part D sponsors on a monthly basis through the Patient Safety Analysis Website. We also recommend adding these measures to the 2018 Part D display measure set (based on 2016 data) to continue to draw attention to the inappropriate use of antipsychotics in persons with dementia without an appropriate mental health diagnosis in both the community and nursing home settings. The APD measure would replace the *Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes* display measure. However, we do not recommend adding this measure to the Star Ratings pending additional research on diagnosis data sources, such as newly available encounter data for Medicare Part C and resolving timing issues of RAPS file updates. We described this plan in the Star Ratings Request for Comment, and we will propose it in the upcoming draft 2017 Call Letter. Additional investigation is also warranted for contracts with outlier APD rates.

Appendix A. Reliability Testing

A mixed effect logistic regression was used with varying intercept to determine whether variation in APD rates across Medicare Part D contracts is statistically significant. Beneficiaries' numerator status (i.e., whether the beneficiary was in the numerator of the APD rate) was modeled based on the varying contract mean:

$$APD\_Numerator_{ic} = U_c + E_i$$

$$U_c = U + n_c$$

Figure 1 provides the Stata output for this analysis. Rows highlighted in green show the relevant output for the reliability analysis. The standard deviation of the intercept term is different from 0 (.301704), as supported by the 95%CI, which we can interpret to mean that APD rates do vary at the contract level. Additionally, the likelihood ratio test shows that the varying intercept model (which allows APD rates to vary across contracts) fits the observed data better than a standard logistic regression model without random effects (which restricts all contracts to have the same average APD rate) with the p-value of 0.

The testing results indicate that the rate variations at the contract level are statistically significant providing evidence that the measure is reliable.

Figure 1: Mixed-effect logistic regression results

```
Mixed-effects logistic regression               Number of obs      =   3757421
Group variable: cc                              Number of groups   =       731

                                                Obs per group: min =         1
                                                               avg =    5140.1
                                                               max =    572815

Integration points =   7                        Wald chi2(0)       =         .
Log likelihood = -1444203.4                     Prob > chi2        =         .

------------------------------------------------------------------------------
aupd_numerator |   Coef.     Std. Err.    Z      P>|z|     [95% Conf. Interval]
---------------+--------------------------------------------------------------
       _cons |  -1.989457   .0130266  -152.72   0.000    -2.014989   -1.963926
------------------------------------------------------------------------------

------------------------------------------------------------------------------
  Random-effects Parameters   |   Estimate   Std. Err.     [95% Conf. Interval]
------------------------------+-----------------------------------------------
cc: Identity                  |
                   sd(_cons) |   .301704   .0107693      .2813179    .3235674
------------------------------------------------------------------------------
LR test vs. logistic regression: chibar2(01) = 10351.38 Prob>=chibar2 = 0.0000
```

Appendix B. PQA Measures of Antipsychotic Use in Persons with Dementia

Antipsychotic Use in Persons with Dementia

Description

The percentage of individuals (65 years and older) with dementia who are receiving an antipsychotic medication without evidence of a psychotic disorder or related condition

Definitions

Measurement Period: The period of time over which the prescription medication fill pattern is assessed.

Eligible Population

Ages: 66 years and older as of the last day of the measurement year.

Continuous enrollment…*using enrollment data:* Subjects should be continuously enrolled during the measurement period. To determine continuous enrollment for a beneficiary for whom enrollment is verified monthly, the member may not have more than a 1-month gap in coverage (i.e., a member whose coverage lapses for 2 months [60 consecutive days] is not considered continuously enrolled).

Proxy for enrollment when using pharmacy only data: Two or more prescriptions for any medication, with 150 days between the first fill and the last fill, over a 12-month period.

Measurement Period: The patient's measurement period begins on the date of the first fill of the target medication (i.e., index date) and extends through the last day of the enrollment period or until death or disenrollment.

Benefit: Pharmacy and Medical.

Event/Diagnosis (Denominator): Identify all eligible patients with either:
1) A diagnosis of dementia *(Table Dementia A)*
and/or
2) Individuals with two or more prescription claims and >60 days supply for a cholinesterase inhibitor or an NMDA receptor antagonist *(Table Dementia B)*

Table Dementia A: Dementia Disease Codes

ICD-9 Codes to Identify Dementia		
290.0 290.1x 290.2x 290.3 290.4x	294.10 294.20	331.0 331.82

Table Dementia B: Cholinesterase Inhibitors and NMDA receptor antagonists

Cholinesterase Inhibitor Medications and NMDA receptor antagonists	
• donepezil • rivastigmine	• galantamine • memantine

Note: The active ingredients are limited to oral and transdermal formulations only.

Administrative Specification
Denominator: The eligible population

Numerator: The number of patients in the denominator who had at least one prescription AND > 30 days supply for any antipsychotic medication during the measurement period *(See Table Dementia C)* and do not have a diagnosis for schizophrenia, bipolar disorder, Huntington's disease or Tourette syndrome (*See Table Dementia D)*

Table Dementia C: Antipsychotic Medications

Antipsychotic Medications		
• Aripiprazole • Asenapine • Chlorpromazine • Clozapine • Fluphenazine • Haloperidol	• Iloperidone • Loxapine • Lurasidone • Olanzapine • Paliperidone • Perphenazine	• Pimozide • Quetiapine • Risperidone • Thioridazine • Thiothixene • Trifluoperazine • Ziprasidone

Note: The active ingredients are limited to oral, sublingual, injectable and intramuscular formulations only. Includes combination products.

Table Dementia D: Disease Codes for specific psychotic disorders or related conditions

ICD-9 Codes to Identify Accepted Indications for Antipsychotic Medications			
Schizophrenia: 295.0x to 295.9x	Bipolar/Manic Disorder: 296.0x 296.1x 296.4x to 296.9x	Huntington's Disease 333.4	Tourette Syndrome 307.23

Measure Calculation

Step One:
Calculate the **denominator** by identifying the number of all eligible patients with either:

1) A diagnosis of dementia *(Table Dementia-A)*
and/or
2) Individuals with two or more prescription claims and >60 days supply for a cholinesterase inhibitor or an NMDA receptor antagonist *(Table Dementia –B)*

Step Two:
Calculate the **numerator** by identifying the number of persons in the denominator who have greater than 30 days supply for any antipsychotic medication during the measurement period. *(See Table Dementia C)*
and
do not have a diagnosis for schizophrenia, bipolar disorder, Huntington's disease or Tourette syndrome *(See Table Dementia D)*

Step Three:
Divide the numerator (step two) by the denominator (step one) and multiply times 100 to calculate the rate as a percentage.

Antipsychotic Use in Persons with Dementia – MDS

Description

The percentage of long-stay nursing home residents with dementia who are persistently receiving an antipsychotic medication without evidence of a psychotic disorder or related condition

The unit of measure is a nursing home facility.

Definitions

Measurement Period: Quarterly using two consecutive time periods with MDS assessment

Long-stay Residents: Residents with Cumulative Days in the Facility (CDIF) greater than or equal to 101 days.

Cumulative Days in the Facility: The total number of days within an episode during which the resident was in the facility. It is the sum of the number of days within each stay included in an episode. If an episode consists of more than one stay separated by periods of time outside the facility (e.g., hospitalizations), only those days within the facility would count towards CDIF. Any days outside of the facility (e.g., hospital, home, etc.) would not count towards the CDIF total.

Antipsychotic Medications: See Table 1

Eligible Population

Ages: 18 years and older on the prior assessment

Skilled Nursing Facility – long–stay residents
Residents with cumulative days in the facility greater than100 days

Administrative Specification

Data Source: MDS 3.0 - Assessment complete in the target quarter and a prior assessment with which to Compare

Assessments can include:
A0130A = {01, 02, 03, 04, 05, 06} or
A0130B = {01, 02, 03, 04, 05, 06} or
A0310F = {10, 11}

A0310A. Federal OBRA
01. Admission
02. Quarterly.
03. Annual.
04. Significant change in status.
05. Significant correction to prior comprehensive.
06. Significant correction to prior quarterly.

A0310B. PPS Assessment.

01. 5-day	02. 14-day	03. 30-day
04. 60-day	05. 90-day	06. Readmission/return assessment

A0310F. Entry/discharge reporting
10. Discharge -return not anticipated.
11. Discharge -return anticipated.

Denominator:
Eligible population with an active diagnosis (Section I) of 14200 Alzheimer's Disease or 14800 Non-Alzheimer Dementia on either the prior or the target assessment and/or if cognitive impairment is indicated based on covariate = 0 in the following definition on either the prior or the target assessment.

Independence or modified independence in daily decision-making for either the prior or target assessment
Covariate = 1 if C1000 = [0, 1] ***or*** if (C0500 ≥ [13] and C0500 ≤ [15])
Covariate = 0 if C1000 = [2, 3] ***or*** if (C0500 ≥ [00] and C0500 ≤ [12]).
Covariate = missing if ***either*** of the following are true:
1. C0500 = [99,-,^] ***and*** C1000 = [-,^].
2. Neither a prior or target assessment is available.

Denominator Exclusions:
Exclude from the Denominator:
Any person in the measurement quarter that does not have a prior assessment and any person where N0410A is missing on either the prior or target assessment

Any person with any of the following Active Diagnoses from Section I in either the prior or the target assessment:
I5250 Huntington's Disease
I5350 Tourette Syndrome
I5900 Manic Depression (bipolar disease)
I6000 Schizophrenia (e.g. schizoaffective and schizophreniform disorders)

Facilities reporting must have 30 or more long-stay residents in the denominator

Numerator:
Patients in the denominator with use of an antipsychotic medication verified in Section N (N0410A) equal to > 12 (days) when combining both assessments.

Table 1 Antipsychotic Medications

Antipsychotic Medications		
• Aripiprazole • Asenapine • Chlorpromazine • Clozapine • Fluphenazine • Haloperidol	• Iloperidone • Loxapine • Lurasidone • Olanzapine • Paliperidone • Perphenazine	• Pimozide • Quetiapine • Risperidone • Thioridazine • Thiothixene • Trifluoperazine • Ziprasidone

Note: The active ingredients are limited to oral, sublingual, injectable and intramuscular formulations only. Includes combination products.