

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**NURSING FACILITY ASSESSMENTS  
AND CARE PLANS FOR RESIDENTS  
RECEIVING ATYPICAL  
ANTIPSYCHOTIC DRUGS**



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## **EXECUTIVE SUMMARY: NURSING FACILITY ASSESSMENTS AND CARE PLANS FOR RESIDENTS RECEIVING ATYPICAL ANTIPSYCHOTIC DRUGS OEI-07-08-00151**

### **WHY WE DID THIS STUDY**

Nursing facilities must meet Federal quality and safety standards to participate in the Medicare and/or Medicaid programs. The standards require extra protections for nursing facility residents receiving antipsychotic drugs. Nursing facility staff are required to assess each resident's functional capacity upon admission to the facility and periodically thereafter. Staff must specify in a written care plan, based on these assessments, the services that each resident needs. The Centers for Medicare & Medicaid Services (CMS) contracts with State agencies to ensure that nursing facilities comply with the standards for resident assessments and care plans.

### **HOW WE DID THIS STUDY**

This study used a random sample of records from a previous Office of Inspector General (OIG) study of elderly nursing facility residents with Medicare claims for atypical antipsychotic drugs between January and June 2007 (OEI-07-08-00150). We reviewed the records for evidence of compliance with Federal requirements for resident assessments and documentation of decisionmaking. We also reviewed the records for evidence of compliance with Federal requirements for care plan development and implementation.

### **WHAT WE FOUND**

Nearly all records reviewed (99 percent) failed to meet one or more Federal requirements for resident assessments and/or care plans. The resident assessment and care plan process involves four steps. One-third of records reviewed did not contain evidence of compliance with Federal requirements regarding resident assessments, the first step. Further, for 4 percent of records, nursing facility staff did not document consideration of the Resident Assessment Protocol for psychotropic drug use as required, the second step. Ninety-nine percent of records did not contain evidence of compliance with Federal requirements for care plan development, the third step. Finally, 18 percent of records reviewed did not contain evidence to indicate that planned interventions for antipsychotic drug use—the fourth step—actually occurred.

### **WHAT WE RECOMMEND**

We recommend that CMS: (1) improve the detection of noncompliance with Federal requirements for resident assessments and care plans for residents receiving antipsychotic drugs, (2) take appropriate action to address noncompliance with these requirements, and (3) provide methods for nursing facilities to enhance the development and usefulness of resident assessments and care plans. CMS concurred with all of our recommendations.

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## OBJECTIVE

To determine the extent to which nursing facilities follow Federal assessment and care plan requirements designed to ensure quality of care for elderly residents receiving atypical antipsychotic drugs.

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## BACKGROUND

Elderly nursing facility residents (residents) receiving atypical antipsychotic drugs are a particularly vulnerable population because of an increased risk of death associated with these drugs.<sup>1,2</sup> A previous Office of Inspector General (OIG) study found that when this population received these drugs, about half of the drugs were not given for medically accepted indications as required for Medicare coverage<sup>3</sup> and one-fifth of the drugs were not given in accordance with Federal safeguards to protect nursing facility residents from unnecessary antipsychotic drug use.<sup>4</sup> This study uses records collected for the previous study to assess the quality of the care provided by nursing facilities to residents receiving atypical antipsychotic drugs.

Nursing facilities must meet Federal quality and safety standards to participate in the Medicare and/or Medicaid programs.<sup>5</sup> To ensure quality of care for residents, the regulations require that nursing facilities provide residents with the services they need to achieve the highest practicable level of well-being.<sup>6</sup> To identify these services, nursing facility staff must assess each resident's functional capacity upon admission to the facility and periodically thereafter.<sup>7</sup> Staff must then specify in a written care plan, based on these assessments, the services that each resident needs.<sup>8</sup>

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<sup>1</sup> Antipsychotic drugs were developed to treat psychoses and/or mood disorders. Atypical antipsychotic drugs are second-generation antipsychotic drugs.

<sup>2</sup> Food and Drug Administration (FDA), *Public Health Advisory: Deaths With Antipsychotics in Elderly Patients With Behavioral Disturbances*, April 2005. Accessed at <http://www.fda.gov> on February 22, 2008.

<sup>3</sup> Medically accepted indications include both the uses approved by FDA and those uses supported by statutorily named compendia. Social Security Act § 1927(g)(1)(B)(i), 42 U.S.C. 1396r-8(g)(1)(B)(i). Medically accepted indications for atypical antipsychotic drugs generally include mental health conditions, such as bipolar disorder, schizophrenia, depression, and psychotic features.

<sup>4</sup> *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* (OEI-07-08-00150), May 2011.

<sup>5</sup> We use the term “nursing facilities” to refer to both skilled nursing facilities and nursing facilities. The former operate under Medicare and the latter under Medicaid; however, both must comply with nearly all of the same requirements. Requirements for the provision of nursing facility services are contained in Social Security Act §§ 1819 and 1919. Federal regulations at 42 CFR pt. 483 and the Centers for Medicare & Medicaid Services (CMS) *State Operations Manual* (SOM), Pub. No. 100-07, provide further interpretation.

<sup>6</sup> 42 CFR § 483.25.

<sup>7</sup> 42 CFR § 483.20(b).

<sup>8</sup> 42 CFR § 483.20(k).

CMS contracts with State agencies to survey nursing facilities and certify those that comply with Federal standards.<sup>9</sup>

### **Protection for Residents Receiving Antipsychotic Drugs**

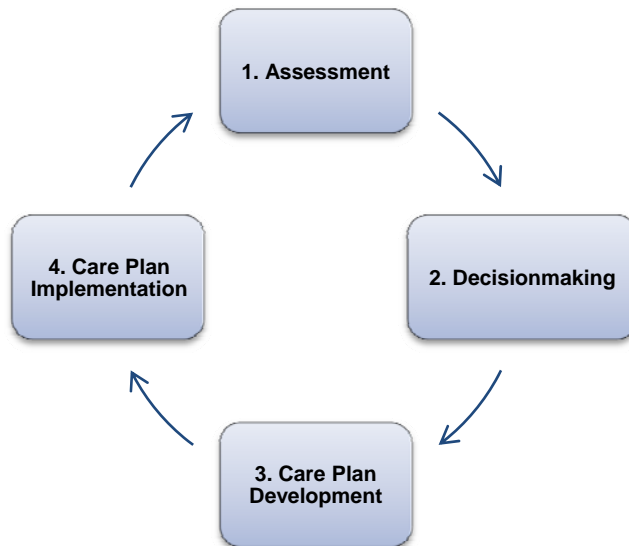
In addition to providing information about the services that residents need, periodic assessments protect residents from receiving services that they do not need. For residents receiving antipsychotic drugs, nursing facilities must ensure, on the basis of comprehensive resident assessments, that:

- residents who have not previously taken antipsychotic drugs are not given them unless it is necessary to treat a specific condition as diagnosed and documented in the residents’ clinical records and
- when antipsychotic drugs are given, residents must receive gradual dose reductions and behavioral interventions in an effort to discontinue the drugs’ use, unless clinically contraindicated.<sup>10</sup>

### **Resident Assessments and Care Plans**

Resident assessments and care plans are critical in providing care. Graphic 1, the “Quality of Care Pathway,” illustrates the importance of each of the four phases involved in providing care. The activities along the pathway can be regarded as a proxy measure for the quality of care provided to nursing facility residents.

**Graphic 1: Quality of Care Pathway**



Source: Adapted from CMS, *Long-Term Care Facility Resident Assessment Instrument (RAI) User’s Manual, version 2.0*, December 2002.

<sup>9</sup> 42 CFR § 488.10.

<sup>10</sup> 42 CFR § 483.25(1)(2).

*Phase One: Assessment.* Federal regulations require nursing facility staff to conduct a comprehensive assessment at the following times: upon resident admission, whenever there has been a significant change in the resident's physical or mental condition, and at least once per year.<sup>11</sup> The initial comprehensive assessments provide baseline information for use in the ongoing assessment of residents' progress.<sup>12</sup>

To ensure that residents are accurately assessed, a qualified health professional correctly documents each resident's medical, functional, and psychosocial issues.<sup>13</sup> The resident's condition determines the appropriate level of involvement of physicians; nurses; rehabilitation therapists; activities professionals; medical social workers; dietitians; and other professionals, such as developmental disabilities specialists.<sup>14</sup> For example, a resident receiving atypical antipsychotic drugs for a mental health condition should be assessed by a mental health professional who is qualified in this specific care area.

A registered nurse (RN) is required to conduct or coordinate each assessment with the participation of other health professionals.<sup>15</sup> In addition, an RN is required to certify that resident assessments are completed.<sup>16</sup>

The Resident Assessment Instrument (RAI) is the tool that nursing facilities must use for preliminary screening to identify potential resident problems, strengths, and preferences.<sup>17</sup> It must contain standardized core items, called the Minimum Data Set (MDS).<sup>18</sup> On October 1, 2010, CMS implemented a new version of the MDS—version 3.0—to improve the MDS's reliability, accuracy, and usefulness; to include the resident in the assessment process; and to use standard protocols used in other settings.<sup>19</sup> See Appendix A for information about changes in MDS 3.0 that may affect assessments of residents receiving antipsychotic drugs.

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<sup>11</sup> 42 CFR § 483.20(b)(2). A significant change is a major improvement or decline in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions; that has an impact on the resident's health status; and that requires interdisciplinary review, revision of the care plan, or both.

<sup>12</sup> CMS, SOM, Pub. No. 100-07, Appendix PP, interpretive guidelines of 42 CFR § 483.20(g).

<sup>13</sup> *Ibid.*

<sup>14</sup> CMS, SOM, Pub. No. 100-07, Appendix PP, interpretive guidelines of 42 CFR § 483.20(h).

<sup>15</sup> 42 CFR § 483.20(h). CMS, SOM, Pub. No. 100-07, Appendix PP, interpretive guidelines of 42 CFR § 483.20(h).

<sup>16</sup> 42 CFR § 483.20(i).

<sup>17</sup> 42 CFR § 483.20(b)(1).

<sup>18</sup> 42 CFR § 483.20(b)(1)(xvii).

<sup>19</sup> CMS, *MDS 3.0 for Nursing Homes and Swing Bed Providers*. Accessed at <https://www.cms.gov> on September 30, 2011.

In addition to performing comprehensive assessments, nursing facilities are required to perform quarterly assessments for each resident at least once every 3 months.<sup>20</sup> These quarterly assessments are designed to ensure that residents' needs are periodically assessed and that their care plans are updated to reflect any identified changes in needs. Each State's quarterly assessment instrument must contain certain mandatory MDS items.<sup>21</sup>

The MDS provides a standard format for Federal documentation requirements and allows nursing facilities to summarize the information in residents' records.<sup>22</sup> Relevant details that are not part of MDS should be documented by nursing facilities elsewhere in resident records, using additional tools for assessment as necessary.<sup>23</sup> The information in nursing facility records should support, rather than conflict with, MDS data reported to CMS.<sup>24</sup>

*Phase Two: Decisionmaking.* Certain combinations of responses to MDS items alert nursing facility staff to potential resident problems, known as "triggered conditions." These triggered conditions guide nursing facility staff to conduct an additional assessment(s) through Resident Assessment Protocols (RAP). Nursing facility staff use RAPs and other clinically relevant assessments to determine whether a triggered condition represents an actual problem for the resident that needs to be addressed in the care plan. Using the assessment information, staff must document in care plans their decisions about whether to proceed with interventions to address triggered conditions.<sup>25</sup>

For residents who receive atypical antipsychotic and other psychotropic drugs,<sup>26</sup> the coding of certain items on the MDS should "trigger" the RAP for psychotropic drug use.<sup>27</sup> For example, if a resident taking an atypical

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<sup>20</sup> 42 CFR § 483.20(c). A minimum of three quarterly assessments are required for each 12-month period, as there are a maximum of 92 days in any 3-month interval.

<sup>21</sup> CMS, SOM, Pub. No. 100-07, Appendix PP, 42 CFR § 483.20(c) interpretive guidelines; and CMS, *Long-Term Care Facility RAI User's Manual, version 2.0*, December 2002.

<sup>22</sup> CMS, *Long-Term Care Facility RAI User's Manual, version 2.0*, December 2002, pp. 1-23. This version of the manual was revised in December 2008; however, we used the 2002 version, as our review period involves nursing facility records from 2007. RAPs were termed "Care Area Assessments" (CAA) in the MDS version 3.0, released in October 2010.

<sup>23</sup> Ibid.

<sup>24</sup> Ibid.

<sup>25</sup> CMS, SOM, Pub. No. 100-07, Appendix PP, 42 CFR § 483.20(k) interpretive guidelines.

<sup>26</sup> Psychotropic drugs include antipsychotic, antidepressant, and anti-anxiety medications for the purposes of MDS 2.0.

<sup>27</sup> Appendix B contains the list of triggers for the Psychotropic Drug Use RAP at the time our data were collected. MDS 3.0, released in October 2010, requires only that a resident received psychotropic drugs prior to the assessment in order to trigger the Psychotropic Drug Use CAA. CMS, *Long-Term Care Facility RAI User's Manual, version 3.0*, September 2010, pp. 4-37.

antipsychotic drug experiences periods of lethargy according to MDS, that observed state should trigger the RAP for psychotropic drug use.<sup>28</sup> Facility staff should then use the RAP to collect additional information about the resident's status to determine whether the lethargy represents a problem related to antipsychotic drug use that should be addressed in the resident's care plan.

*Phase Three: Care Plan Development.* Nursing facilities are required to develop a care plan for each resident within 7 days after the completion of the comprehensive assessment and to review it after all subsequent (comprehensive and quarterly) resident assessments.<sup>29</sup> Care plans should describe the services that the nursing facility will provide to residents to assist them in attaining or maintaining the highest practicable functional status.<sup>30</sup> Care plans include measurable objectives and timeframes to meet residents' physical, mental, and psychosocial needs.<sup>31</sup>

Interdisciplinary teams composed of the attending physician, the RN overseeing the resident's care, and "other appropriate staff in disciplines as determined by the resident's needs" must prepare a care plan for each resident.<sup>32</sup> Care plan development also requires participation, to the extent practicable, of the resident or the resident's family or legal representative.<sup>33</sup> Appendix C provides an example of how a resident assessment is used to help develop a care plan intervention for antipsychotic drug use.

*Phase Four: Care Plan Implementation.* In general, care plans list several physical, medical, and psychosocial objectives based on resident strengths or problems; interventions to address risks related to those objectives; and periodic evaluations of progress towards the goal. Figure 1 shows an example of what might be included in a care plan to address risks associated with antipsychotic drug use.

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<sup>28</sup> Appendix B indicates signs, symptoms, and conditions for using the RAP for psychotropic drug use. CMS, *Long-Term Care Facility RAI User's Manual, version 2.0*, December 2002, pp. C-87.

<sup>29</sup> 42 CFR § 483.20(k)(2).

<sup>30</sup> 42 CFR § 483.20(k)(1).

<sup>31</sup> Ibid.

<sup>32</sup> Ibid.

<sup>33</sup> 42 CFR § 483.10(d)(3), 42 CFR § 483.20(k)(2)(ii), and interpretive guidelines at CMS, SOM, Pub. No. 100-07, Appendix PP. The facilities are responsible for assisting residents and/or their representatives with participation in care plans.



**Figure 1. Care Plan Example**

Problem/Objective	Intervention	Evaluation
Resident is at risk for side effects of antipsychotic drug use. Goal: Reduce risk of side effects.	<ul style="list-style-type: none"> <li>• Attempt gradual dose reduction of antipsychotic drug at least once per quarter.</li> <li>• Monitor resident for side effects, especially lethargy.</li> </ul>	<ul style="list-style-type: none"> <li>• Dose reduction occurred 2 months ago and was well tolerated.</li> <li>• Resident experienced lethargy only 2 of the last 30 days.</li> <li>• Action: Continue interventions as stated.</li> </ul>

Source: OIG analysis of nursing facility records, 2011.

Federal regulations require that nursing facilities provide necessary care and services to each resident in accordance with the resident’s comprehensive assessment and care plan.<sup>34</sup> To achieve this, the facility staff must continually implement and update the care plan.<sup>35</sup> Interpretive guidelines state that nursing facilities must ensure that each resident “obtains optimal improvement or does not deteriorate” within the limits of the normal aging process.<sup>36</sup> That is, care plans can be used to correct physical or emotional problems, if possible, or ensure that a resident does not experience an avoidable decline in health. Nursing facility staff reevaluate the resident’s status using the RAI and then modify the care plan as necessary.<sup>37</sup>

### State Certification Process

To participate in Medicare and Medicaid, nursing facilities must be certified.<sup>38</sup> States certify nursing facilities through a process that determines compliance with Federal standards, including standards for resident assessments and care plans.<sup>39</sup> In this process, State surveyors identify deficiencies and score them using severity and scope. The deficiencies identified on State surveys have implications for nursing facilities’ participation in Medicare.<sup>40</sup> To rate the quality of each nursing facility on its publicly available *Nursing Home Compare* Web site CMS uses health inspection ratings from State surveys, nursing facility staffing information, and quality measures from MDS.<sup>41</sup> Consumers can compare

<sup>34</sup> 42 CFR § 483.25 and § 483.20(k)(3)(ii).

<sup>35</sup> CMS, SOM, Pub. No. 100-07, Appendix PP, interpretive guidelines for 42 CFR § 483.25.

<sup>36</sup> Ibid.

<sup>37</sup> CMS, *Long-Term Care Facility RAI User’s Manual, version 2.0*, December 2002, pp. 4-27.

<sup>38</sup> Requirements for the provision of nursing facility services are contained in Social Security Act §§ 1819 and 1919. Federal regulations at 42 CFR § 483 and the CMS SOM, Pub. No. 100-07, provide further interpretation.

<sup>39</sup> CMS, SOM, Pub. No. 100-07, ch. 1 § 1016—Approval and Correction of Deficiencies.

<sup>40</sup> 42 CFR § 488.330

<sup>41</sup> CMS, “Five-Star Quality Rating System.” Accessed at <https://www.cms.gov> on December 22, 2011.

these quality ratings to evaluate how nursing facilities may differ from one another.<sup>42</sup>

When identifying deficiencies, State surveyors determine the accuracy of residents' comprehensive (MDS) assessments and the adequacy of care plans using those assessments. However, no guidance explains specifically how deficiencies in resident assessments and care plans should be scored. See Appendix D for more information about the State certification process for nursing facilities.

### **Previous Office of Inspector General Reports**

Previous OIG studies used medical review to examine the accuracy of the MDS in resident assessments and care plans at skilled nursing facilities.<sup>43</sup> Medical reviewers identified inconsistencies between responses in MDS and documentation in residents' medical records. For example, medical reviewers identified documentation in nursing facility records representing triggered conditions; however, staff did not indicate in the MDS that these conditions were present. Thus, MDS did not "trigger" RAPs and staff did not consider triggered conditions in care plans.

Additional OIG work has focused on the timeliness of resident assessments and submission of required MDS data.<sup>44</sup> OIG found that nursing facilities generally performed resident assessments and submitted MDS data within required timeframes, but did not always code MDS data accurately. In contrast to previous OIG reports, this report does not examine the accuracy of MDS data.

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## **METHODOLOGY**

We selected a random sample of nursing facility records for elderly residents receiving atypical antipsychotic drugs. We reviewed the records for evidence of compliance with Federal requirements for resident assessments and care plans.

### **Data Collection**

*Scope.* This study used a sample of records from a previous OIG study of elderly nursing facility residents with Medicare claims for atypical antipsychotic drugs during the first 6 months of 2007.<sup>45</sup> During the

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<sup>42</sup> CMS, "Understanding Nursing Home Quality Measures." Accessed at <http://www.medicare.gov> on December 22, 2011.

<sup>43</sup> *Nursing Home Resident Assessment Quality of Care* (OEI-02-99-00040), January 2001; *Supplemental Data on the Minimum Data Set* (OEI-02-02-00831), August 2005; and *Questionable Billing by Skilled Nursing Facilities* (OEI-02-09-00202), December 2010.

<sup>44</sup> *Facility Performance in Assessing Residents and Submitting MDS Records* (OEI-06-02-00730), April 2005.

<sup>45</sup> *Medicare Claims for Atypical Antipsychotic Drugs in Nursing Homes* (OEI-07-08-00150), May 2011.

previous study, geriatric psychiatrists reviewed these residents' records to determine facility compliance with Medicare requirements for administering atypical antipsychotic drugs. Because all previously sampled residents had Medicare claims for atypical antipsychotic drugs, this study used those residents' records to focus on nursing facility use of the RAP for psychotropic drug use during resident assessments and care plans.

*Sample Selection.* For this study, we reviewed 375 records randomly selected from the 640 nursing facility records collected for the previous study. During the previous study, we requested nursing facility records corresponding to a sample of 700 Medicare claims (from a universe of 1,678,874 claims) for atypical antipsychotic drugs for elderly residents from January 1 through June 30, 2007 (our review period).<sup>46</sup> These prescription drug claims from the previous study were associated with 304,983 elderly nursing facility residents, representing 14 percent of the total elderly nursing facility population during the review period.<sup>47</sup>

We did not project our results for this study to the universe of residents from the previous study because the basis for sampling for the previous study was claims rather than residents. We also did not project our results for this study to the original universe of claims corresponding to the nursing facility records, as the nursing facility regulatory requirements that we reviewed in this study are not applicable to prescription drug claims.

*Record Review.* We used the Medicare beneficiary nursing facility records for the 6 months before and after the date of the sampled Medicare claims, which were collected for the previous study. We developed a data collection instrument to determine the extent to which nursing facilities met Federal requirements for resident assessments and for care plans, according to documentation in the nursing facility records. We reviewed the records for comprehensive assessments, quarterly assessments, and care plans. We determined whether the records indicated that nursing facility staff complied with Federal requirements for (1) resident assessments, (2) decisionmaking, (3) care plan development, and (4) care plan implementation.

*Resident Assessments.* We determined whether the requisite number of comprehensive and quarterly assessments were present in the record. We adjusted our analysis, when applicable, according to residents' dates of

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<sup>46</sup> See Appendix E for detailed information about how the sampling methodology for the previous study affects this study.

<sup>47</sup> The previous study excluded payments for atypical antipsychotic drugs provided under the Medicare Part A Prospective Payment System for short-term stays in skilled nursing facilities because they are not individually quantifiable on the basis of claims data.

death during our review period. For example, if a resident's date of death occurred 4 months before the end of our 12-month review period, we did not expect to see at least one comprehensive assessment and all three quarterly assessments in the record, nor did we consider those records to be noncompliant. Similarly, if a resident was admitted to the nursing facility in the middle of our review period, we adjusted our analysis of timeliness accordingly.

We also reviewed assessments for staff involvement. We noted the credentials of staff listed as participants in completing comprehensive and quarterly assessments. When the MDS had a location for an RN to sign indicating RN coordination of the comprehensive assessment or of the RAP assessment process, we assumed the signatures to be those of RNs even if the individual signing the form did not list his or her credentials. If the signature was missing from the relevant assessment section or the relevant assessment section was missing entirely, we considered the record noncompliant.

*Decisionmaking.* We reviewed comprehensive assessments to determine whether the nursing facility staff documented their care plan decisions when the RAP for psychotropic drug use was triggered. For example, if this RAP was triggered because a resident taking an atypical antipsychotic drug experienced an unsteady gait, we reviewed the RAP summary to determine whether nursing facility staff (1) attributed the unsteady gait to antipsychotic drug use or another cause and (2) determined whether the unsteady gait represented a problem for the resident that needed to be addressed in the care plan. When staff documented a decision, we noted the facility's intention to proceed (or not to proceed) with inclusion of an intervention in the care plans.

*Care Plan Development.* We reviewed care plans for timeliness (i.e., developed within 7 days of each comprehensive assessment) and evidence that they were developed by an interdisciplinary team composed of at least a physician and an RN and that the resident or the resident's family or legal representative was involved. We noted the credentials of staff listed as participants in developing the care plan, including mental health professionals, such as psychologists or psychiatric or geriatric specialty-trained physicians. When involvement of the resident or the resident's family or legal representative was not documented within the care plan, we reviewed care plan information, intake forms, social work notes, and nursing notes to determine whether nursing facility staff documented why their involvement was not practicable. For example, if the intake form indicated that the resident was incompetent and the social worker noted that he or she was not successful in contacting the resident's family or legal representative regarding a care plan update, we determined

that the involvement of the resident or the resident's family or legal representative was not practicable and that the nursing facility complied with this requirement.

*Care Plan Implementation.* We reviewed mental health assessments, medication administration records, and logs of behavior and drug side effects to determine whether interventions occurred as stated in the care plans. For example, if a care plan stated that the nursing facility would monitor the resident for side effects, such as unsteady gait, and would attempt gradual dose reductions, we reviewed the record for evidence of those interventions. We reviewed care plans for evidence of interventions to address psychotropic drug use regardless of whether the RAP for psychotropic drug use was triggered and/or considered in the development of the care plan. We also reviewed records for evidence of interventions to address psychotropic drug use regardless of whether they were listed in the care plans.

### **Data Analysis**

Using SAS (a statistical analysis software package), we analyzed data collected during our record review. We calculated the proportion of sampled records that included evidence indicating that:

- comprehensive and quarterly assessments were conducted during the time intervals required and by qualified health professionals;
- care plans included consideration of interventions for triggered RAPs;
- care plans were created timely, were prepared by an interdisciplinary team, and involved the resident or the resident's family or legal representative; and
- care plans were implemented as described with respect to interventions for antipsychotic drug use.

Given the nature of our study population, our review of the involvement of health professionals in resident assessments and care plans focused on those most qualified to assess complex mental health and medical conditions, including physicians, psychologists, social workers, and RNs. We did not review the involvement of other staff, such as activities professionals, nutritionists, licensed practical nurses, or nurse's aides.

Additionally, our review determined whether assessments were present in records during the general time intervals required rather than the precise timeliness of such items. For example, we determined how many quarterly and annual assessments were present rather than whether each quarterly assessment was performed exactly 92 days from the previous assessment date. This method may have overestimated nursing facility

compliance with Federal requirements for timeliness of resident assessments.

### **Limitations**

Our analysis was limited by the information available in the nursing facility records and interpretation of those records provided previously by medical reviewers. Neither the medical reviewers nor the study team members conducted in-person observations of the residents or interviews with the residents, residents' families or legal representatives, or clinical staff to evaluate compliance with Federal requirements.

To determine compliance with the requirement that care plan development include the resident, the resident's family, or the resident's legal representative "to the extent practicable," we reviewed whether attempts at inclusion were documented. While no explicit requirement exists that a nursing facility document its efforts to include the resident, family, or legal representative, documentation was the most feasible way to assess compliance with the requirement.

We did not determine whether comprehensive assessments were conducted when a significant change in resident status occurred, because the medical reviewers did not note those occurrences.<sup>48</sup>

We determined the extent to which the RAP for psychotropic drug use was used to create care plans. However, we did not determine the medical appropriateness of care plans or of the antipsychotic drugs prescribed for residents.

Although the medical records we reviewed are from a period prior to implementation of MDS 3.0, we are unaware of any MDS changes or other changes in nursing facility practice that materially affect the findings in this report.

### **Standards**

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

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<sup>48</sup> 42 CFR § 483.20(b)(2).

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## FINDING

### **Nearly all records reviewed failed to meet one or more Federal requirements for resident assessments and/or care plans**

Overall, 373 of the 375 records reviewed for elderly nursing facility residents receiving atypical antipsychotic drugs during the first 6 months of 2007 lacked evidence to indicate that they met all Federal requirement(s) for nursing facility resident assessments and care plans. The resident assessment and care plan process involves four steps. One-third of records did not contain evidence of staff compliance with Federal requirements regarding resident assessments, the first step. For 4 percent of records, nursing facility staff did not document consideration of the RAP for psychotropic drug use as required, the second step. Additionally, 99 percent of records did not contain evidence that Federal requirements for care plans—the third step—were met. Finally, 18 percent of records that listed care plan interventions for antipsychotic drug use did not contain evidence that those interventions—the fourth step—actually occurred. Forty-eight percent of records did not meet two or more Federal requirements, resulting in 205 overlapping errors.<sup>49</sup>

Table 1 summarizes records that did not meet Federal requirements for resident assessments and care plans. Further details regarding each type of requirement follow the table.

Table 1: Records That Did Not Contain Evidence That Federal Requirements Were Met

<b>Federal Requirements Not Documented</b>	<b>Records (n=375)</b>	<b>Percentage</b>
Resident Assessments	125	33.3%
Decisionmaking (Consideration of RAP for psychotropic drug use)	15	4.0%
Care Plan Development	371	98.9%
Care Plan Implementation	67	17.9%
Overlapping	(205)	(54.6%)
<b>Total (net)</b>	<b>373</b>	<b>99.5%</b>

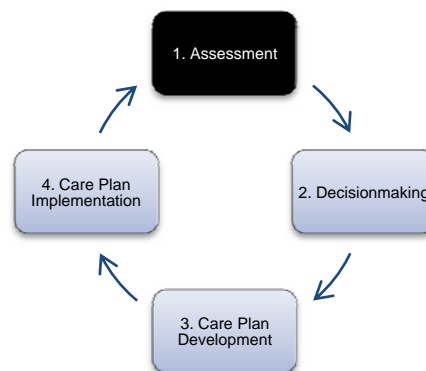
Source: OIG analysis of nursing facility records, 2011.

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<sup>49</sup> Note that a single record may have multiple errors and thus the percentage overlap would be equal to or greater than the percentage of records with overlapping errors.

## One-third of records reviewed did not contain evidence of compliance with Federal requirements regarding resident assessments

To meet Federal requirements, nursing facility staff must conduct at least one comprehensive resident and three quarterly assessments per year. Comprehensive assessments and RAP assessments must be coordinated by an RN. Overall, 125 of 375 records did not meet Federal requirements regarding resident assessments, according to the documentation



provided. Nine percent of records did not meet more than one Federal requirement for resident assessments, resulting in 34 overlapping errors. Table 2 shows the number and percentage of records that did not comply with Federal requirements for resident assessments.

Table 2: Records That Did Not Contain Evidence That Federal Requirements for Resident Assessments Were Met

Federal Requirements Not Documented	Records (n=375)	Percentage
Lacked required quarterly assessments	106	28.3%
Lacked required comprehensive assessments	43	11.5%
Comprehensive assessments not coordinated by RN	0	0.0%
RAP assessments not coordinated by RN	10	2.7%
Overlapping	(34)	(9.1%)
<b>Total (net)</b>	<b>125</b>	<b>33.3%</b>

Source: OIG analysis of nursing facility resident records, 2011.

As listed in Table 2, 28 percent of records did not include required quarterly assessments and 12 percent of records did not include required comprehensive assessments. No records that contained the required assessments lacked evidence of an RN's coordination of comprehensive assessments; however, 10 such records lacked evidence of an RN's coordination of the RAP assessment.

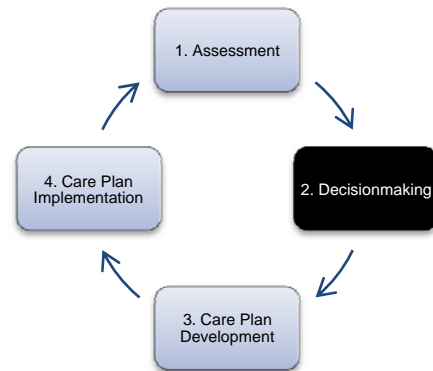
Although RN involvement in resident assessments was generally evident, records contained little evidence of involvement by a professional who was qualified in the relevant care area, such as a mental health professional. Despite the fact that residents had mental health conditions



that needed to be assessed by qualified health professionals, no psychiatrists or geriatricians were involved with resident assessments and only one record contained evidence that a psychologist was involved. In fact, 46 percent of records indicated that an RN was solely responsible for conducting the resident assessment. See Appendix F for a listing of professionals involved in the comprehensive resident assessments for this population, illustrating the lack of involvement of mental health professionals.

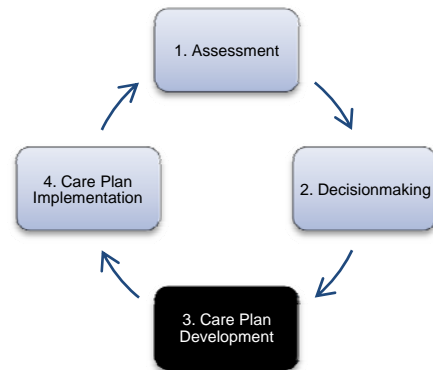
**For 4 percent of records reviewed, nursing facility staff did not document consideration of the RAP for psychotropic drug use as required**

Nursing facility staff must document their decisionmaking regarding whether triggered conditions for RAPs require care plans. Nursing facility staff did not document consideration of the RAP for psychotropic drug use for 15 of the 375 records reviewed. Additionally, of the 277 records that indicated that the staff intended to develop care-plan interventions for psychotropic drug use, 14 percent (39 of 277) did not contain evidence that the staff actually did so. Of the 98 records that indicated that staff did *not* intend to develop care-plan interventions for psychotropic drug use, 54 percent (53 of 98) contained evidence that the staff developed such interventions, further illustrating a disconnection in the decisionmaking process between resident assessments and care plans.



**Ninety-nine percent of records reviewed did not contain evidence of compliance with Federal requirements for care plan development**

To meet Federal requirements, a care plan must (1) be developed within 7 days after the completion of a comprehensive assessment, (2) be prepared by an interdisciplinary team consisting of at least a physician and an RN, and (3) include involvement of the resident or the resident’s family or legal representative to the extent practicable. Table 3 shows the number and percentage of records that did not contain evidence of compliance with Federal requirements for care plans. Sixty-six percent of



records did not contain evidence for more than one Federal requirement for care plans, resulting in 271 overlapping errors.

Table 3: Records That Did Not Contain Evidence That Federal Requirements for Care Plan Development Were Met

Federal Requirements Not Met	Records (n=375)	Percentage
No care plan documentation was provided	23	6.1%
Care plans were not developed timely	35	9.3%
Care plans did not include evidence of resident/family/representative involvement or documentation as to why it was impracticable	221	58.9%
Care plans were not developed by interdisciplinary team (physician and RN)	363	96.8%
Overlapping	(271)	(72.2%)
<b>Total (net)</b>	<b>371</b>	<b>98.9%</b>

Source: OIG analysis of nursing facility resident records, 2011.

Six percent of records did not include care plans, and 9 percent of records contained care plans that were not developed or updated within the required 7 days from the completion of comprehensive assessments. Less than 5 percent of records contained care plans developed by the required interdisciplinary team of at least a general physician and an RN.

A psychiatrist, geriatrician, or psychologist should also be involved in developing care plans, given that they are the appropriate, qualified practitioners to assess the mental health conditions among our study population. However, only two care plans involved such practitioners. Moreover, 20 percent of records indicated that an RN, a social worker, or a licensed practical nurse was solely responsible for developing the care plan.<sup>50</sup> Of the 12 records that involved a physician, 2 records indicated that the physician signed the care plan but did not actually attend the care plan development conference. See Appendix F for a listing of the professionals that were involved in care plans for our study population, showing the lack of mental health professionals.

Though the participation of the resident, family, or legal representative in developing care plans is required only “to the extent practicable,” such participation is important to ensure that residents receive quality care. Overall, 91 percent of records did not contain evidence that the resident, the resident’s family, or the resident’s legal representative participated in

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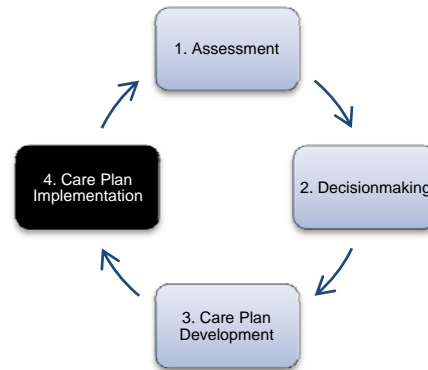
<sup>50</sup> These records are included in the measure of care plans not developed by an interdisciplinary team.

the care plan process. Nearly two-thirds of those records, or 59 percent of all records, also lacked documentation as to why such participation did not occur (i.e., why participation was not practicable).

**Eighteen percent of records reviewed did not contain evidence to indicate that planned interventions for antipsychotic drug use occurred**

Nursing facilities must provide necessary services to residents in accordance with their written care plans. Interventions for psychotropic drug use listed in care plans included monitoring for side effects and effectiveness of the drugs and attempting gradual dose reductions.

For 18 percent of records reviewed, nursing facility staff listed such interventions in residents' care plans, but the records contained no evidence that those interventions occurred. For example, one resident's care plan listed as an intervention a gradual dose reduction for the antipsychotic drug within a certain quarter, but the record contained no evidence in the medication log, pharmacist's review, or elsewhere that a dose reduction was attempted. Also, in several of these cases, the facilities had forms—such as side-effect logs or behavioral logs—designed to measure the intervention, but those forms were either blank or incomplete. An additional 23 percent of records reviewed did not list any interventions for psychotropic drug use. Overall, of the records we reviewed of elderly nursing facility residents receiving atypical antipsychotic drugs, 41 percent contained no indications that the residents received relevant interventions.



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## CONCLUSION AND RECOMMENDATIONS

In striving to ensure quality of care for residents, nursing facilities must provide residents with the services they need to achieve their highest practicable level of well-being. Nursing facilities identify services through periodic assessments of each resident's functional capacity and specify these services in a written care plan for each resident. Facility noncompliance with the requirements for resident assessments and care plans may negatively affect the services that residents receive, thereby placing their quality of care at risk.

Overall, 99.5 percent of records reviewed for elderly nursing facility residents receiving atypical antipsychotic drugs did not contain evidence that all Federal requirements for nursing facility resident assessments and care plans were met. For one-third of records, nursing facility staff did not complete resident assessments in accordance with Federal requirements. For 4 percent of records, nursing facility staff did not document consideration of the RAP for psychotropic drug use as required. Ninety-nine percent of records did not contain evidence that care plans were developed in accordance with Federal requirements. Finally, for 18 percent of records, records contained no evidence that interventions for antipsychotic drug use listed in the care plans actually occurred. Forty-eight percent of records did not meet more than one type of requirement. The extent of the noncompliance identified suggests increased risks for this already vulnerable population.

To ensure that nursing facilities take actions designed to provide high-quality care to elderly residents in nursing facilities, we recommend that CMS:

### **Improve the detection of noncompliance with Federal requirements for resident assessments and care plans**

Although this study targeted residents receiving antipsychotic drugs, CMS should aim to eliminate nursing facility deficiencies in resident assessments and care plans for all residents. CMS should also consider modifying the survey process to target a small subsample of residents receiving antipsychotic drugs, focusing on the quality of care for these particularly vulnerable residents.

In addition, CMS should consider strengthening guidance in the SOM for issues for which Federal regulations for resident assessment and care plans do not explicitly require documentary evidence. For example, CMS could require that nursing facilities document any efforts to include the participation of residents, their families, or their legal representatives in the development of care plans. Surveyors' determination of compliance with requirements for care plan development may be more expeditious and reliable if based on documentation rather than on the recollection of residents, their families or legal representatives, or nursing facility staff.

## **Take appropriate action to address noncompliance with Federal requirements for resident assessments and care plans**

CMS should ensure that both the rate of detection and the sanctions for survey deficiencies are significant enough to deter noncompliance. CMS could accomplish this by clarifying in the SOM which deficiency determinations and enforcement remedies are most appropriate for deficiencies in resident assessments and care plans. For example, CMS could indicate whether residents are placed in an “immediate jeopardy” status when interventions listed in care plans are not provided.

To promote nursing facility compliance, CMS should also explore alternative methods beyond the State survey and certification process. CMS could consider incentive programs for nursing facilities and/or prescribing physicians for providing high-quality resident assessment and care plan services. To bring consumer awareness to this issue, CMS could also consider adding to the publicly available *Nursing Home Compare* Web site one or more quality measures reflecting deficiencies in resident assessment and care plans.

## **Provide methods for nursing facilities to enhance the development and usefulness of resident assessments and care plans for residents receiving antipsychotic drugs**

CMS could accomplish this by:

- forming a task force of qualified health professionals (e.g., geriatric psychiatrists, psychologists, social workers) to recommend best practices for resident assessments and care plans for nursing facility residents receiving antipsychotic drugs;
- exploring novel ways to ensure that nursing facilities have access to the expertise of qualified mental health professionals (e.g., through remote consultations or interactive informational Web sites) when assessing and developing care plans for residents receiving antipsychotic drugs;
- providing nursing facility staff with training on the importance of care plan interventions, especially for residents receiving antipsychotic drugs; and
- encouraging nursing facilities to complete the applicable forms when providing care plan interventions, such as monitoring residents’ moods, behaviors, and drug side effects.

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with all of our three recommendations. CMS has recently launched a national initiative to improve behavioral health and dementia care and to reduce the use of antipsychotic drugs in nursing homes by 15 percent by the end of 2012. CMS noted that that the information in this report will be helpful in its efforts to improve the care of all individuals residing in nursing homes, not only those receiving antipsychotic medications.

With regard to our first recommendation, CMS plans to strengthen guidance for surveyors in the SOM to improve the detection of noncompliance with Federal requirements for resident assessments and care plans. CMS also recently expanded the sampling strategy for the Quality Indicator Survey to ensure sufficient representation of residents receiving antipsychotic drugs. If resources permit, CMS plans to test a focused review of resident assessments, care plans, and medication use in a sample of nursing facilities.

With regard to our second recommendation, CMS plans to clarify guidance in the SOM on which deficiency determinations and enforcement remedies are most appropriate for deficiencies in resident assessments and care plans and to include this clarification in upcoming surveyor training programs. CMS plans to develop—through a partnership with consumer organizations—educational materials to increase consumer awareness of antipsychotic drug use in nursing facilities. CMS also plans to post a new quality indicator on the publicly available *Nursing Home Compare* Web site regarding the prevalence of antipsychotic drug use among long-term residents with dementia who have not been diagnosed with specific psychotic disorders.

With regard to our third recommendation, CMS has a multidisciplinary approach to reduce the unnecessary use of antipsychotic drugs that includes public-private partnerships; research; technical assistance and education (for nursing homes, physicians/prescribers, pharmacists, nurses, and others); consumer engagement; public reporting; and updates to surveyor guidance and training. A technical expert panel recently advised CMS regarding provider training and technical assistance, quality indicators, surveyor training, and improvements to surveyor guidance.

The full text of CMS's comments is provided in Appendix G. We did not make any changes to the report based on CMS's comments.

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## APPENDIX A

### Changes to the Minimum Data Set, Version 3.0, That May Affect the Assessments of Residents Receiving Antipsychotic Drugs

#### Cognitive Assessment:

- The Brief Interview for Mental Status (BIMS) structured test replaces the staff assessment for residents who can understand the interview questions and respond.
- Facilities complete the staff assessment for mental status only for residents who cannot complete the BIMS.
- The Validated Confusion Assessment Method (CAM) replaces the MDS 2.0 delirium items, which were not reliable.

#### Mood Assessment:

- The Patient Health Questionnaire nine-item depression scale (PHQ-9) resident interview replaces staff observations for residents who can report mood symptoms.
- This scale is based on well-established diagnostic criteria for depression.

#### Behavior Items:

- Items regarding hallucinations and psychosis were moved from a list of several other behaviors to a subsection about psychosis where definitions for hallucinations and delusions were added to the form.
- Language describing physical and verbal behavioral symptoms was revised for clarification.
- “Wandering” is now rated separately from the other behavioral symptom groups.

#### Resident Assessment Protocol (RAP) for psychotropic drug use:

- The RAP is now called the Psychotropic Drug Use Care Area Assessment (CAA).
- Whereas the RAP was triggered by combination triggers in MDS 2.0 (listed in Appendix B), the CAA—its successor—is triggered simply by use of an antipsychotic, antianxiety, antidepressant, or hypnotic medication administered to the resident in the 7 days preceding the assessment.

Source: Centers for Medicare & Medicaid Services (CMS), *Long-Term Care Facility Resident Assessment Instrument User's Manual, version 3.0*, September 2010; CMS, *Minimum Data Set (MDS)*, accessed at <https://www.cms.gov> on May 14, 2011; and CMS, *MDS 3.0: The Why & How* (presentation from MDS 3.0 National Training Conference), August 2010, accessed at <https://www.cms.gov> on May 11, 2011.

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## APPENDIX B

### Triggers for the Resident Assessment Protocol for Psychotropic Drug Use

[FOR THE RESIDENT ASSESSMENT PROTOCOL (RAP)] TO BE TRIGGERED, RESIDENT MUST FIRST USE A PSYCHOTROPIC DRUG (antipsychotic, antidepressant, or antianxiety). If used, go to Resident Assessment Protocol review if one or more of the following [is] present:\*

Potential for drug-related hypotension or gait disturbances if:

- Repetitive Physical Movement
- Balance While Sitting
- Hypotension
- Dizziness/Vertigo
- Syncope
- Unsteady Gait
- Fell in Past 30 Days
- Fell in Past 31-180 Days
- Hip Fracture
- Swallowing Problem

Potential for drug-related discomfort if:

- Constipation
- Fecal Impaction
- Lung Aspiration

Potential for drug-related cognitive/behavioral impairment if:

- Delirium/Disordered Thinking
  - Easily Distracted
  - Periods of Altered Perception or Awareness of Surroundings
  - Episodes of Disorganized Speech
  - Periods of Restlessness
  - Periods of Lethargy
  - Mental Function Varies Over the Course of the Day
- Deterioration in Cognitive Status
- Deterioration in Communication
- Deterioration in Mood
- Deterioration in Behavioral Symptoms
- Depression
- Hallucinations

Source: Centers for Medicare & Medicaid Services (CMS), *Long-Term Care Facility Resident Assessment Instrument [RAI] User's Manual, version 2.0*, December 2002.

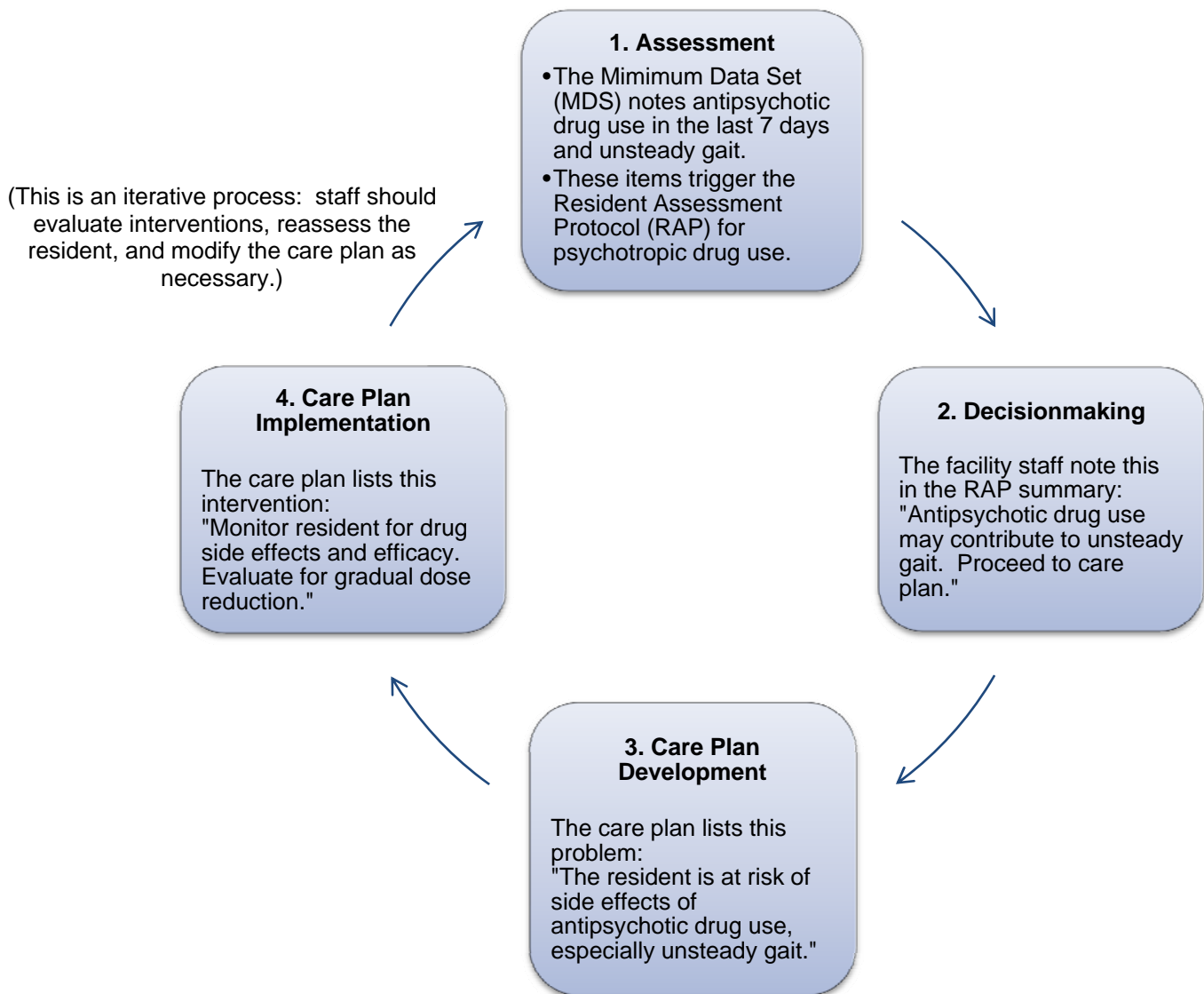
\*Minimum Data Set 3.0, released October, 2010, now uses Care Area Assessments (CAA) for triggered conditions instead of RAPs. The only condition to trigger the Psychotropic Drug Use CAA is that the resident received psychotropic drugs in the 7 days prior to the assessment. CMS, *Long-Term Care Facility RAI User's Manual, version 3.0*, September 2010.



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## APPENDIX C

### Example of How a Resident Assessment Is Used To Develop a Care Plan Intervention for Antipsychotic Drug Use



Source: Office of Inspector General analysis of nursing facility records, 2011.

Note: MDS 3.0, released October, 2010, now uses Care Area Assessments (CAA) for triggered conditions instead of RAPs. The only condition to trigger the Psychotropic Drug Use CAA is that the resident received psychotropic drugs in the 7 days prior to the assessment. Centers for Medicare & Medicaid Services, *Long-Term Care Facility Resident Assessment Instrument User's Manual, version 3.0*, September 2010.

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## APPENDIX D

### State Certification of Nursing Facilities

#### General Process

State agencies certify nursing facilities as compliant or noncompliant with Federal standards for health and safety. This determination is based on a survey conducted by qualified health professionals that verifies whether and how each standard is met. Surveys are generally unannounced and must be conducted at a minimum of every 15 months for each facility. If deficiencies are identified, they are categorized by severity (i.e., effect on resident outcome) and scope (i.e., number of residents potentially or actually affected), and the State sends the facility a Statement of Deficiencies. Facilities have 10 days to respond with a Plan of Correction for each cited deficiency. If an acceptable plan is not submitted or if a facility does not correct deficiencies, the State and/or the Centers for Medicare & Medicaid Services (CMS) may impose remedies, such as civil money penalties, temporary managers, directed plans of correction, in-service training, denial of payment for new admissions, and State monitoring.

*Survey tasks.* State surveys generally include: offsite survey preparation, an entrance conference and onsite preparation, an initial tour of the facility, and a sample selection of residents. Information for the sampled residents is gathered through activities such as observations; informal and formal interviews with residents, staff, family, and others; and record review. Surveyors analyze this information to identify any deficiencies and then hold an exit conference with the facility.

*Deficiency determinations.* When a facility is not in substantial compliance with Federal standards, the facility may have the opportunity to correct deficiencies before remedies are imposed. This depends on the severity and scope of the deficiencies. Severity levels should reflect psychosocial (i.e., mood and behavior) outcomes as well as physical outcomes. There are four severity levels, ranging from no actual harm with potential for minimal harm (Level 1) to immediate jeopardy to resident health or safety (Level 4). Immediate jeopardy requires immediate corrective action because of actual or potential serious injury, harm, impairment, or death to a resident. When determining scope, surveyors consider the cause of the deficiency. Scope has three levels: isolated, pattern, and widespread. If a facility lacks an adequate system to meet a requirement and this failure has the potential to affect a large number of residents, the deficiency is likely to be widespread.

*Remedy Categories.* There are three categories of enforcement remedies (see Table D-1). Denial of payment for new admissions must be imposed when a facility is not in substantial compliance within 3 months of being found out of compliance. Denial of payment and State monitoring must be imposed when a facility provides substandard quality of care as

determined by three consecutive standard surveys. See Table D-2 for a matrix of enforcement remedies for deficiencies based on severity and scope.

**Table D-1: Remedy Categories**

Category 1	Category 2	Category 3
Directed plan of correction	Denial of payment for new admissions	Temporary management
State monitor; and/or	Denial of payment for all individuals imposed by CMS; and/or	Termination
Directed in-service training	Civil money penalties: \$50 - \$3,000/day \$1,000 - \$10,000/instance	Optional: Civil money penalties \$3,050 - \$10,000/day \$1,000 - \$10,000/instance

Source: CMS, *State Operations Manual*, Pub. No. 100-07, ch. 7.

**Table D-2: Enforcement Remedies Based on Severity and Scope of Deficiencies**

Deficiency Severity	Remedy Category	Deficiency Scope		
		Isolated	Pattern	Widespread
Actual or potential for death or serious injury (immediate jeopardy)	Required	3	3	3
	Optional	1, 2	1, 2	1, 2
Actual harm that is not immediate jeopardy	Required	2	2	2
	Optional	1	1	1
Potential for more than minimal harm	Required	1	1	2
	Optional	2	2	1
Potential for minimal harm; substantial compliance exists	Required	None	Plan of Correction	Plan of Correction

Source: CMS, *State Operations Manual*, Pub. No. 100-07, ch. 7.

### **Resident Assessments and Care Plans\***

Surveyors are instructed to evaluate assessments, care plans, and outcomes of care interventions for sampled residents. Surveyors determine whether the facility has properly assessed its residents through the completion of the Resident Assessment Instrument (RAI) and has appropriately developed, implemented, and evaluated care plans. They use observations, interviews, and record review to conduct a comprehensive review, including the following:

- a check of specific items on the Minimum Data Set (MDS) for accurate coding of the resident's condition;
- a review of the facility's completion of the RAI process, including use of the Resident Assessment Protocols (RAP), evaluation of assessment information not covered by the RAPs, identification of risks and causes of resident conditions, completion of the RAP summary sheet, and development of a care plan that meets the identified needs of the resident;
- a review of the implementation of the care plan and resident response; and
- a review of the relationship of the resident's drug regimen to the resident's condition, including whether the effectiveness of the regimen is being monitored and assessed.

When reviewing the RAIs and care plans, surveyors:

- review the RAP summary sheet to determine:
  - where the assessment documentation is located for triggered RAPs and
  - whether the facility used the RAPs and considered necessary information when deciding to proceed or not proceed with care plans and
- review the care plan to identify:
  - whether the facility used the RAI to make sound care plan decisions and
  - whether the facility implemented the interventions listed in the care plan.

Surveyors use this information to determine whether a resident's decline or failure to improve was avoidable or unavoidable. Surveyors also determine whether a reassessment based on a significant change should have been conducted and whether the absence of a reassessment contributed to the resident's decline or lack of improvement. Record reviews of information, of care plans, of implementation of care plans, and of evaluations of care enable surveyors to determine whether there has been a decline, an improvement, or maintenance in identified focus areas.

The *State Operations Manual* does not provide specific guidance to surveyors regarding how deficiencies in resident assessments and care plans should be scored and/or when they might place residents in immediate jeopardy.

Source: CMS, *State Operations Manual*, Pub. No. 100-07, chs.1 and 7, Appendixes P and Q.

\* MDS 3.0, released October, 2010, now uses Care Area Assessments (CAA) for triggered conditions instead of RAPs. As a result, State surveyors now use CAAs instead of RAPs during their reviews.

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## APPENDIX E

### Sample Selection

The sample size for the original study (700) was chosen to accommodate stratification by resident diagnoses. (For additional information, see *Medicare Claims for Atypical Antipsychotic Drugs in Nursing Homes*, OEI-07-08-00150, May 2011). This stratification scheme was not relevant to the current study. Therefore, we randomly selected fewer records from the original sample to expedite our review for this study while allowing for adequate precision when reporting results.

We reviewed a subset of 375 records for this study that were originally collected for the previous study. The original sample of 700 claims included 59 cases from facilities that did not respond to our record request, which are not represented in this study. The original sample also included 40 cases with records that were not submitted timely and were therefore not submitted for medical review. Twenty-four of those 40 cases were included in this review but did not contain data from the previous medical record review. Table E-1 shows how the original sample for the previous study relates to the sample for this study.

Table E-1: Characteristics of Current Sample Based on Previous Study

Study	Sample Size	Nonrespondents	Did Not Receive Medical Review
Previous	700	59	40
Current	375	n/a	24

Source: Office of Inspector General selection of study sample, 2010.

We conducted analysis to determine whether the errors in this study correlated with the errors in the previous study. There were no statistically significant correlations between the two sets of variables. Therefore, our results for this study do not appear to be biased by the absence of information from those records that did not previously undergo medical review.

## APPENDIX F

### Professionals Involved in Resident Assessments and Care Plans

**Table F-1: Professionals Involved in Resident Assessments**

Professionals	Number (Exclusive*)	Percentage	Number (Inclusive**)	Percentage
Psychiatric Physician	0	0.0%	0	0.0%
Geriatric Physician	0	0.0%	0	0.0%
Psychologist	0	0.0%	1	0.3%
General Physician	0	0.0%	4	1.1%
Social Worker	15	4.0%	103	27.5%
Registered Nurse	172	45.9%	261	69.6%

\*The indicated staff member was solely responsible for resident assessments.

\*\*The indicated staff member was responsible for resident assessments as part of a group including one or more staff members from other disciplines.

Source: Office of Inspector General (OIG) analysis of nursing facility resident records, 2011.

**Table F-2: Professionals Involved in Care Plans**

Professionals	Number (Exclusive*)	Percentage	Number (Inclusive**)	Percentage
Psychiatric Physician	0	0.0%	0	0.0%
Geriatric Physician	0	0.0%	0	0.0%
Psychologist	0	0.0%	2	0.5%
General Physician	0	0.0%	12	3.2%
Licensed Practical Nurse	13	3.5%	49	13.1%
Social Worker	13	3.5%	160	42.7%
Registered Nurse	50	13.3%	195	52.0%

\*The indicated staff member was solely responsible for resident assessments.

\*\*The indicated staff member was responsible for resident assessments as part of a group including one or more staff members from other disciplines.

Source: OIG analysis of nursing facility resident records, 2011.

## APPENDIX G

### Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator  
Washington, DC 20201

MAY 30 2012

TO: Daniel R. Levinson  
Inspector General

FROM: ~~Martin T. Tanner~~ /S/  
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs (OEI-07-08-00151)

Thank you for the opportunity to review the subject OIG draft report on nursing facility assessments and care plans for residents receiving atypical antipsychotic drugs. The Centers for Medicare & Medicaid Services (CMS) appreciates the OIG's valuable contributions toward improving the lives of nursing home residents. CMS has taken action through a national initiative to improve behavioral health and dementia care and to reduce the use of antipsychotic drugs in nursing homes by 15 percent by the end of calendar year 2012. Some details of CMS' initiative are included in the recommendation sections below. We appreciate that the information in this OIG draft report will be helpful in our efforts to improve the care of all individuals residing in nursing homes, not only those on antipsychotic medications.

In the following remarks we provide our response to each individual OIG recommendation.

#### OIG Recommendation

To ensure that nursing facilities take actions designed to provide high-quality care to elderly residents in nursing facilities, we recommend that CMS improve the detection of noncompliance with Federal requirements for resident assessments and care plans.

#### CMS Response

CMS concurs. CMS plans to strengthen the *State Operations Manual* directions for surveyors to review documentation of resident and family involvement in assessment and care planning, as well as assessing compliance with regulations through interviews with residents and families. Further, we recently implemented the new Minimum Data Set (MDS) 3.0 system, as a system which incorporates improvements that were not present in the MDS 2.0 (and hence not available for the OIG study). In particular, MDS 3.0 requires facilities to interview residents and staff rather than solely looking at paper records. CMS believes that improving detection of noncompliance during the survey process should also rely on both the medical record and staff and resident or family interviews. New surveyor guidance in development will emphasize these principles.

With regard to modifying the survey process to target a sample of residents receiving antipsychotic medications, CMS recently expanded the sampling strategy for the Quality Indicator Survey (QIS) in a manner that is responsive to this recommendation. The amended sampling strategy will increase the number of residents that are reviewed during each standard survey who are receiving an antipsychotic medication. This will ensure that sufficient samples of residents who are receiving antipsychotics are included in all surveys.

Subject to resources, in fiscal year 2013 we will pilot-test a focused review of resident assessments, care plans and medication use in a sample of nursing homes. This focused review will provide us with even more information about improvements that may be needed in our overall surveyor guidance, process and training.

**OIG Recommendation**

To ensure that nursing facilities take actions designed to provide high-quality care to elderly residents in nursing facilities, we recommend that CMS take appropriate action to address noncompliance with Federal requirements for resident assessments and care plans.

**CMS Response**

CMS concurs with the recommendation to clarify guidance in the State Operations Manual on which deficiency determinations and enforcement remedies are most appropriate for deficiencies in resident assessments and care plans. CMS will include any clarifications to policy revisions as well as existing policy in upcoming surveyor training programs.

CMS also concurs with the OIG suggestion to increase consumer awareness on this issue. We are exploring a partnership with a number of consumer organizations for the development of specialized consumer education materials on the use of antipsychotic medications in nursing homes.

Specifically related to antipsychotic medication use, we plan to post a new quality indicator (QI) by the summer of 2012 on CMS' Nursing Home Compare website. We expect that the main QI measure will focus on the prevalence of antipsychotic medication use in long-stay residents with dementia who do not have schizophrenia, Tourette's syndrome or Huntington's disease. CMS also plans to post a short-stay incidence indicator (the number of short-stay residents who enter the facility who are not on an antipsychotic who are started on an antipsychotic medication after skilled nursing facility/nursing facility admission). CMS believes that the public reporting of these quality indicators will encourage nursing homes to improve assessments, care plans, and other aspects of care so as to reduce unnecessary antipsychotic medications.

**OIG Recommendation**

To ensure that nursing facilities take actions designed to provide high-quality care to elderly residents in nursing facilities, we recommend that CMS provide methods for nursing facilities to



enhance the development and usefulness of resident assessments and care plans for residents receiving antipsychotic drugs.

**CMS Response**

CMS concurs. CMS has a multidimensional approach to improving behavioral health assessment and care planning including interventions to reduce the unnecessary use of antipsychotic medications. This approach involves—(1) Public-private partnerships; (2) Research; (3) Technical assistance and education for nursing homes, physicians/prescribers, pharmacists, nurses and others; (4) Consumer engagement; (5) Public reporting; and (6) Updates to surveyor guidance and surveyor training. CMS is working with numerous partners, such as consumer groups, professional associations that represent nursing home administrators, directors of nursing, physicians and other prescribers, medical directors, pharmacists, certified nursing assistants and other direct care workers, advocacy organizations, researchers, policy-makers, and other agencies within the Department of Health and Human Services. These partner organizations are developing technical assistance for providers that will include enhanced assessment and care planning related to dementia and dementia-related behaviors and use of antipsychotic drugs.

Surveyor guidance (in development) will direct surveyors to review records and interview staff, residents and families to identify compliance with Federal requirements for assessment and care planning. CMS plans to issue a survey and certification policy memo to introduce this enhanced guidance. CMS has already begun production on two surveyor training programs that will be mandatory.

CMS also concurs with the recommendation to enlist qualified health professionals to advise us. Our Agency benefitted from a technical expert panel (TEP) convened by *Advancing Excellence* on April 10 and 11, 2012. This group included nationally-renowned consumer representatives, geriatric psychiatrists, geriatricians, nurses, social workers, nursing home representatives, quality improvement organization leadership, advocates and family members. The expert participants provided ideas on provider training and technical assistance, quality indicators, surveyor training, and potential improvements to surveyor guidance for residents receiving antipsychotic medications. The discussions also provided ideas relevant to assessment and care planning. As a result of the TEP and work by CMS' partnering organizations, tools and resources for providers have already begun to appear on the *Advancing Excellence* website home page ([www.nhqualitycampaign.org](http://www.nhqualitycampaign.org)).

We appreciate the opportunity to comment on this draft report, and we look forward to working with OIG on this and other issues.

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## ACKNOWLEDGMENTS

This report was prepared under the direction of Brian T. Pattison, Regional Inspector General for Evaluation and Inspections in the Kansas City regional office, and Brian T. Whitley, Deputy Regional Inspector General.

Julie Dusold Culbertson served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Kansas City regional office who conducted the study include Rae Hutchison and Dennis Tharp. Central office staff who provided support include Kevin Farber, Sandy Khoury, and Christine Moritz.

# Office of Inspector General

<http://oig.hhs.gov>

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The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## **Office of Audit Services**

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

## **Office of Evaluation and Inspections**

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

## **Office of Investigations**

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

## **Office of Counsel to the Inspector General**

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.