

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**AVAILABILITY OF MEDICARE  
PART D DRUGS TO  
DUAL-ELIGIBLE NURSING HOME  
RESIDENTS**



Daniel R. Levinson  
Inspector General

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# *Office of Inspector General*

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## OBJECTIVE

To assess the availability of Medicare Part D drugs to dual-eligible nursing home residents.

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## BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Medicare Prescription Drug Program, known as Medicare Part D. The Centers for Medicare & Medicaid Services (CMS) contracts with private health insurance companies that sponsor Part D plans. Each Part D plan develops its own list of covered drugs, known as a formulary, and may also use utilization management tools, such as prior authorization, to control drug costs and dosages. Nursing homes typically have contracts with long-term care pharmacies to ensure safety and convenient access to drugs for residents. Under Part D, CMS requires that each plan offer a contract to any long-term care pharmacy that is willing to participate in its network.

Dual-eligible beneficiaries are eligible to receive both Medicare and Medicaid coverage. Prior to Medicare Part D, Medicaid paid for most of the prescription drugs for dual-eligible nursing home residents. Under Part D, these residents now receive drug coverage through Medicare, and are eligible to have their premiums, deductibles, and copayments fully subsidized.

This study focuses on ongoing implementation issues, as opposed to the issues related to the transition from Medicaid to Medicare that arose in the early stages of the benefit. It is based on structured interviews with a sample of nursing home administrators, medical directors, and directors of operations for long-term care pharmacies (referred to as pharmacy directors) conducted between September 2006 and March 2007.

Estimates derived from administrators' responses are projected to the population of administrators of nursing homes with dual-eligible residents. However, estimates derived from medical directors' and pharmacy directors' responses are limited to the sample respondents due to a low response rate and low usable sample size, respectively.

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## FINDINGS

**Most respondents reported that dual-eligible nursing home residents are receiving all necessary Part D drugs.** Ninety-three percent of nursing home administrators reported that dual-eligible residents in their nursing homes are receiving all necessary Part D drugs. About 4 percent of administrators reported that at least one dual-eligible resident in each of their nursing homes is not receiving needed drugs from their Part D plans or any other sources. They explained that some of these residents changed their Part D plans or were transferred to hospitals to receive the drugs they needed; others went without the drugs entirely. The majority of medical directors and pharmacy directors whom we interviewed also reported that dual-eligible nursing home residents are receiving all necessary Part D drugs.

**Nursing homes and long-term care pharmacies sometimes pay for Part D drugs that are not covered by plans.** Forty-five percent of administrators reported that their nursing homes paid for at least one Part D drug for dual-eligible residents. As several administrators explained, nursing homes may pay for these Part D drugs to comply with Federal regulations and Conditions of Participation that require nursing homes to ensure that residents receive needed drugs in a timely manner. Additionally, 77 percent (61 of 79) of the pharmacy directors whom we interviewed reported that their pharmacies paid for at least one Part D drug for dual-eligible residents in the sampled nursing homes. Administrators and pharmacy directors explained that the drugs they most commonly pay for either are not on the residents' plans' formularies or require prior authorization. Several pharmacy directors explained that not all plans cover the cost of a short-term supply of drugs during the prior authorization process.

**Respondents express concerns that formularies, the prior authorization process, and copayments may pose problems for dual-eligible nursing home residents.** About one-fifth of nursing home administrators and a similar proportion of the medical directors and pharmacy directors whom we interviewed are concerned that plan formularies may not meet all of the needs of some dual-eligible nursing home residents. For instance, several medical directors noted that the therapeutically equivalent drugs on the formulary are not always appropriate for residents because they may cause adverse side effects or may not be in the proper form. Additionally, about one-fifth of administrators and a similar proportion of the medical directors and

pharmacy directors expressed concerns that the prior authorization process can be burdensome. The majority of pharmacy directors also reported that some dual-eligible residents are being incorrectly identified as required to pay copayments.

**Concerns also exist that long-term care pharmacies generally do not disclose to physicians the rebates that they receive from drug manufacturers.** According to our interviews, long-term care pharmacies have continued to receive rebates from drug manufacturers under Part D and they generally do not disclose these rebates to physicians. More than half of the pharmacy directors whom we interviewed reported that their pharmacies receive rebates from drug manufacturers, but only three of these pharmacy directors reported that their pharmacies provide any information to nursing homes or to physicians about the rebates that they receive. Pharmacists employed by these long-term care pharmacies can influence the drugs that are prescribed to residents in nursing homes both when drugs are initially ordered and during monthly drug regimen reviews. Taken together, these issues raise concerns that rebates may create incentives for pharmacists and consultant pharmacists to recommend certain drugs over others based on financial considerations as opposed to clinical considerations and that physicians may not be aware of these incentives when deciding whether to take pharmacists' recommendations.

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## RECOMMENDATIONS

Based on these findings, we plan to do additional work on long-term care pharmacy rebates. In addition, we recommend that CMS take the following actions:

**Work with plans to ensure that formularies meet the needs of dual-eligible nursing home residents.** During its formulary review process, CMS should put additional emphasis on ensuring that plans include the drugs and alternative dosages and forms that meet the needs of dual-eligible nursing home residents.

**Continue to work with plans to improve the prior authorization process.** CMS should clarify existing guidance to ensure that plans pay for a supply of drugs for current enrollees during routine prior authorization requests. Further, CMS should specify under what circumstances a supply of drugs would qualify as being an emergency supply. CMS should also work with plans to ensure that plan staff are

responsive and knowledgeable about Part D formulary and coverage issues that are specific to dual-eligible nursing home residents.

**Ensure that copayments for dual-eligible nursing home residents are fully subsidized, as appropriate.** CMS should continue its efforts to ensure that residents are properly identified as dually eligible and as residing in nursing homes. CMS should also work with plans to ensure they are using “best available data” when they have knowledge that a beneficiary is being inappropriately charged copayments. CMS should also consider educating long-term care pharmacies and nursing homes about what “best available data” they can provide to plans.

**Consider methods to encourage long-term care pharmacies to disclose to physicians information about rebates that they receive from drug manufacturers.** We recognize that CMS does not have the authority under Part D to require long-term care pharmacies to disclose the rebates that they receive from drug manufacturers. However, CMS can consider methods to encourage long-term care pharmacies to disclose to physicians information about their rebates. Because long-term care pharmacists can influence the drugs that are prescribed to residents in nursing homes, it is important that physicians be aware of any potential financial incentives that pharmacists may have to recommend one drug over another.

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with two of our recommendations and the intent of the third recommendation; it did not concur with our last recommendation. CMS stated that it will work with plans to ensure that formularies meet the needs of dual-eligible nursing home residents and continue to work with plans to improve the prior authorization process. CMS concurred with the intent of our third recommendation to ensure that copayments for dual-eligible residents are fully subsidized, as appropriate. CMS did not concur with our fourth recommendation to consider methods to encourage long-term care pharmacies to disclose to physicians information about rebates that they receive from drug manufacturers. CMS stated that it does not have authority under Part D to require long-term care pharmacies to disclose their rebates to physicians. We recognize that CMS does not have the authority to require pharmacies to disclose rebate information to physicians. However, we continue to recommend that CMS consider additional ways to encourage pharmacies to disclose this information to physicians so that they are

## E X E C U T I V E   S U M M A R Y

aware of any potential financial incentives that pharmacists may have to recommend one drug over another.

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## OBJECTIVE

To assess the availability of Medicare Part D drugs to dual-eligible nursing home residents.

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## BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Medicare Prescription Drug Program, known as Medicare Part D.<sup>1</sup> The Part D benefit provides prescription drug coverage for Medicare beneficiaries, including dual-eligible beneficiaries who are eligible to receive both Medicare and Medicaid coverage. Approximately one in four dual-eligible beneficiaries resides in a long-term care facility such as a nursing home.<sup>2</sup> This benefit is particularly important for nursing home residents, who frequently have multiple chronic diseases and take an average of 8 to 10 medications a day.<sup>3</sup>

The implementation of Part D significantly changed prescription drug coverage for dual-eligible nursing home residents. Prior to Medicare Part D, Medicaid paid for most of the prescription drugs for dual-eligible nursing home residents. Under Part D, these residents now receive drug coverage through Medicare and must enroll in private Part D prescription drug plans.

This study focuses on ongoing implementation issues, as opposed to the issues related to the transition from Medicaid to Medicare that arose in the early stages of the benefit. It provides information on the extent to which dual-eligible residents are receiving needed drugs under Part D and identifies issues specific to this population.

### **The Medicare Prescription Drug Benefit**

The Centers for Medicare & Medicaid Services (CMS) contracts with private health insurance companies, known as sponsors, to

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<sup>1</sup> MMA, P.L. No. 108-173, title I, § 101 et seq. (codified at 42 U.S.C. § 1395w-101 et seq. and 42 U.S.C. § 1396u-5).

<sup>2</sup> Government Accountability Office, “Medicare Part D Challenges in Enrolling New Dual-Eligible Beneficiaries,” May 2007, p. 11.

<sup>3</sup> The Lewin Group, “CMS Review of Current Standards of Practice for Long-Term Care Pharmacy Services: Long-Term Care Pharmacy Primer,” December 30, 2004, p. 1.

provide the Medicare Part D benefit. These sponsors may offer a stand-alone prescription drug plan (PDP) or they can offer prescription drug coverage as a part of a managed care plan known as a Medicare Advantage Prescription Drug Plan (MA-PD). Throughout this report, we will refer to PDPs and MA-PDs as Part D plans.

On January 1, 2006, dual-eligible nursing home residents were automatically enrolled in randomly assigned eligible Part D plans if they had not already selected one.<sup>4</sup> Unlike other Medicare beneficiaries, dual-eligible beneficiaries may change their plans at any time.<sup>5</sup> Further, dual-eligible nursing home residents are eligible to have any premiums, deductibles, or copayments fully subsidized for prescription drugs covered under Medicare Part D.<sup>6</sup>

### **Formularies and Utilization Management Tools**

Each Part D plan develops its own list of covered drugs, known as a formulary, which must meet certain standards. Each plan's formulary must contain at least two drugs within each therapeutic category and pharmacologic class.<sup>7</sup> It must also cover "all or substantially all" of the drugs in six categories: immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes.<sup>8</sup> CMS reviews each plan's formulary to ensure that it provides access to appropriate treatments for all diseases and is not designed to discourage enrollment by any particular group.

Certain classes of drugs are excluded from coverage by Part D. These include benzodiazepines, barbiturates, weight management drugs, and over-the-counter drugs.<sup>9</sup> Furthermore, Part D generally excludes from coverage any drug that is covered under Part A or Part B.<sup>10</sup> Several factors must be considered to determine whether a drug is covered under Part A, B, or D, such as setting, characteristics of the patient, medical use of the drug

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<sup>4</sup> 42 U.S.C. § 1395w-101(b)(1)(C); see also 42 CFR § 423.34.

<sup>5</sup> 42 CFR § 423.38(c)(4).

<sup>6</sup> 42 U.S.C § 1395w-114; see also 42 CFR §§ 423.780 and 423.782.

<sup>7</sup> 42 CFR § 423.120(b)(2)(i).

<sup>8</sup> CMS, "Prescription Drug Benefit Manual," Chapter 6—Part D Drugs and Formulary Requirements, § 30.2.5.

<sup>9</sup> 42 U.S.C. § 1395w-102(e)(2)(A) and 42 U.S.C. § 1396r-8(d).

<sup>10</sup> 42 U.S.C. § 1395w-102(e)(2)(B).

and its form, and the method of administration.<sup>11</sup> CMS issued guidance in its Prescription Drug Benefit Manual which details the circumstances under which Parts A, B, and D cover drugs.

Plans may use utilization management tools to control drug costs and dosages.<sup>12</sup> These tools include prior authorization, step therapy, or quantity limitations. As is generally known, prior authorization requires a beneficiary to seek prior approval from the plan to receive a drug on the formulary. Step therapy requires the beneficiary to try a less-expensive alternative drug before the plan will cover a specific drug. Quantity limitations restrict the amount of the drug that can be prescribed or the number of refills per prescription.

Plans must have an exceptions process whereby beneficiaries may request that the plan cover a drug that is not on the formulary.<sup>13</sup> Additionally, beneficiaries may appeal adverse coverage determinations through an appeals process.<sup>14</sup> In 2006, CMS collaborated with the American Medical Association and America's Health Insurance Plans to develop a standardized form for the exceptions and prior authorization processes. Although plans are allowed to have their own forms, they are required to accept this form.<sup>15</sup>

In addition, CMS provided guidance to plans about covering nonformulary drugs under certain circumstances. For 2006, CMS required plans to have a transition policy and recommended that they provide nursing home residents who are new enrollees with temporary supplies of nonformulary drugs for 90 to 180 days. CMS also encouraged plans to cover one-time supplies of drugs for current enrollees during the exceptions process and for

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<sup>11</sup> CMS, "Prescription Drug Benefit Manual," Chapter 6—Part D Drugs and Formulary Requirements, Appendix C-1 and C-2. Available online at: [http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqmts\\_03.09.07.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqmts_03.09.07.pdf). Accessed on November 7, 2007.

<sup>12</sup> 42 CFR § 423.153.

<sup>13</sup> 42 CFR § 423.578.

<sup>14</sup> 42 U.S.C. § 1395w-104(h).

<sup>15</sup> CMS, "Frequently Asked Questions: Coverage Determination Request Forms, Physician Supporting Statements & Processing Timeframes for Exceptions and Prior Authorizations." Available online at [http://www.rxassist.org/providers/documents/CMSAppealsExceptionsFAQs\\_000.pdf](http://www.rxassist.org/providers/documents/CMSAppealsExceptionsFAQs_000.pdf). Accessed on October 31, 2007.

beneficiaries who were transitioning into new care settings, such as nursing homes.<sup>16</sup> For 2007, CMS required plans to cover a 90-day supply of nonformulary drugs and drugs requiring prior authorization or step therapy for new enrollees who are nursing home residents.<sup>17</sup> Further, CMS required plans to provide up to a 31-day emergency supply of nonformulary Part D drugs and drugs requiring prior authorization or step therapy for current nursing home residents while an exception is being processed.

### **Long-Term Care Pharmacies**

Nursing homes typically have contracts with long-term care pharmacies to ensure safety and convenient access to drugs for residents.<sup>18</sup> Given the resident population's needs, these pharmacies provide specialized services, such as a comprehensive inventory of drugs commonly used in long-term care settings, specialized packaging, intravenous therapy medications, 7-day-a-week delivery, pharmacy on-call services, and emergency medications.<sup>19</sup> Under Part D, CMS requires that each plan offer a contract to any long-term care pharmacy that is willing to participate in its network and is capable of meeting minimum performance and service criteria.<sup>20</sup>

Long-term care pharmacies have historically received rebates from drug manufacturers. According to CMS, these rebates are intended to “prefer, protect, or maintain that manufacturer’s product selection by the pharmacy or to increase the volume of

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<sup>16</sup> CMS, “Information for Part D Sponsors on Requirements for a Transition Process, March 2005.” Available online at [http://www.ascp.com/medicarerx/upload/transition\\_process.pdf](http://www.ascp.com/medicarerx/upload/transition_process.pdf). Accessed on October 31, 2007.

<sup>17</sup> CMS, “Transition Process Requirements for Part D Sponsors, April 2006.” Available online at <http://www.ascp.com/medicarerx/upload/CY07TransitionGuidance.pdf>. Accessed on October 12, 2007.

<sup>18</sup> 70 Fed. Reg. 4194, 4250 (Jan. 28, 2005).

<sup>19</sup> CMS, “Long-Term Care Guidance, March 16, 2005.” Available online at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/LTCGuidance.pdf>. Accessed on July 31, 2007.

<sup>20</sup> 70 Fed. Reg. 4251; see also *ibid.*

that manufacturer's products that are dispensed by the pharmacy under its formulary (referred to as 'moving market share').<sup>21</sup> Beginning in 2007, long-term care pharmacies are required to report to the Part D plans with which they contract the rebates that they receive.<sup>22</sup>

### **Federal Requirements for Nursing Homes**

Federal law requires nursing homes to ensure that residents are provided with all drugs needed to fulfill the residents' plans of care.<sup>23</sup> Specifically, as a condition of participation in the Medicare or Medicaid programs, nursing homes must provide or arrange for the provision of "pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident."<sup>24</sup> If a nursing home enters into a contract with a pharmacy to provide pharmaceuticals, the nursing home is responsible for the quality and timeliness of pharmaceutical care and services.<sup>25</sup> CMS guidance also instructs nursing homes to provide these drugs in a timely manner and as ordered by the prescriber.<sup>26</sup>

Federal regulations also require nursing homes to arrange for a pharmacist to review each resident's drug regimen at least monthly.<sup>27</sup> Most nursing homes contract with licensed pharmacists, commonly known as consultant pharmacists, to conduct these drug regimen reviews. Consultant pharmacists must report any irregularities they find during these reviews to

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<sup>21</sup> CMS, "Medicare Part D Reporting Requirements, Contract Year 2007." Available online at [http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements\\_CurrentYear.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements_CurrentYear.pdf). Accessed on October 5, 2007.

<sup>22</sup> Ibid.

<sup>23</sup> A plan of care describes the medical, nursing, and psychosocial needs of the resident and how such needs will be met; see 42 U.S.C. § 1396r(b)(2)(A).

<sup>24</sup> 42 U.S.C. § 1396r (b)(4)(A)(iii); see also 42 CFR § 483.60.

<sup>25</sup> 42 CFR § 483.75(h).

<sup>26</sup> Noncompliance can result in a citation during the routine survey process. 42 CFR § 483.75(h); see also CMS, "State Operations Manual, Appendix PP—Guidance to Surveyors for Long-Term Care Facilities," Rev. 26, 8-17-07, pp. 430 and 442.

<sup>27</sup> 42 CFR § 483.60(c).

the attending physician and the director of nursing and these reports must be acted upon.<sup>28</sup>

### **Related Work**

The Medicare Payment Advisory Commission (MedPAC) recently issued a report entitled “Medicare Part D, Nursing Homes, and Long-Term Care Pharmacies.”<sup>29</sup> The report found that many stakeholders described Part D as a better fit for beneficiaries in the community than for beneficiaries in institutions such as nursing homes. Stakeholders noted that although formulary coverage appears adequate for many medications used by nursing home residents, they had concerns about obtaining certain drugs and about utilization management tools being burdensome for clinical and pharmacy staff.

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## **METHODOLOGY**

### **Scope**

We based this study on our analysis of structured interviews with a sample of nursing home administrators, medical directors, and directors of operations for long-term care pharmacies who have firsthand knowledge about Part D for dual-eligible nursing home residents. We conducted these interviews between September 2006 and March 2007.

### **Sample**

We selected a simple random sample of 150 nursing homes from CMS’s Online Survey and Certification Reporting database. We limited our sample to all nursing homes that had at least 10 Medicaid-certified or dually certified (both Medicare- and Medicaid-certified) beds. We excluded 6 of the 150 sampled nursing homes from our review because they informed us that they did not have any dual-eligible residents in 2006. Our sample included the remaining 144 nursing homes.

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<sup>28</sup> Ibid.

<sup>29</sup> MedPAC, “Medicare Part D, Nursing Homes, and Long-Term Care Pharmacies,” June 2007. Available online at [http://www.medpac.gov/documents/Jun07\\_Part\\_D\\_Contractor.pdf](http://www.medpac.gov/documents/Jun07_Part_D_Contractor.pdf). Accessed on October 5, 2007.

**Nursing Home Administrators**

We conducted structured telephone interviews with each of the administrators at the nursing homes in our sample. We also requested that the director of nursing participate in the interview, if possible.

We asked each administrator about his or her experiences with Medicare Part D for dual-eligible residents. We focused our questions on whether dual-eligible residents are receiving all necessary Part D drugs, i.e., drugs that are eligible for coverage under Part D.<sup>30</sup> We also asked what happens when a resident needs a drug that is not on his or her plan's formulary or needs a drug that is on the formulary but has utilization management requirements, such as prior authorization. Further, we asked what, if any, concerns they had about Part D for dual-eligible residents.

We interviewed a total of 128 administrators from the 144 sample nursing homes, resulting in an 89-percent response rate. According to the administrators, approximately 7,800 dual-eligible residents lived at these nursing homes at the time of our review. Appendix A provides confidence intervals for selected estimates.

**Nursing Home Medical Directors**

We conducted structured telephone interviews with each of the medical directors for the nursing homes in our sample. The medical director is responsible for the implementation of resident care policies and the coordination of medical care at the facility.<sup>31</sup> The director may also serve as the attending physician for residents in the nursing home.

We asked each medical director questions similar to those that we asked the administrators. We interviewed a total of 95 medical directors from the 144 sampled nursing homes, resulting in a 66-percent response rate.

**Directors of Operations for Long-Term Care Pharmacies**

We conducted structured telephone interviews with each of the directors of operations of the long-term care pharmacies for the

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<sup>30</sup> We gave all respondents explicit instructions related to excluded drugs and reminded them throughout the interview not to consider excluded drugs when answering the questions.

<sup>31</sup> 42 CFR § 483.75(i)(2)(i)-(ii).

nursing homes in our sample. The nursing homes contracted with a total of 139 long-term care pharmacies. We excluded 55 of these pharmacies from our study because they were under investigation by the Office of Inspector General (OIG) at the time of our review. We conducted interviews with a total of 79 directors of operations from the remaining 84 long-term care pharmacies.

We asked each director of operations questions similar to those that we asked the other respondents. In addition, we asked them about the nature and extent of any rebates that they receive from drug manufacturers. We included these questions because of concerns that CMS officials raised. For the purposes of our report, we refer to these respondents as pharmacy directors.

### **Limitations**

The information from our interviews with the administrators, medical directors, and pharmacy directors is self-reported; we did not independently verify their responses. Estimates derived from administrators' responses are projected to the population of administrators of nursing homes with dual-eligible residents. However, estimates derived from medical directors' and pharmacy directors' responses are limited to the sample respondents. We did not project these estimates to the population due to the low response rate and low useable sample size, respectively.

Further, we did not collect information about individual residents, such as their length of stay at a nursing home. In addition, we did not interview consultant pharmacists.

### **Standards**

Our review was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.



**Most respondents reported that dual-eligible nursing home residents are receiving all necessary Part D drugs**

Ninety-three percent of nursing home administrators reported that dual-eligible residents in their nursing homes are receiving all necessary Part D drugs.<sup>32</sup>

(See Table 1.) Administrators explained that physicians typically order drugs that are on the formularies of the residents’ plans. When a drug is not on the formulary or requires prior authorization, generally the

physician changes the prescription to a drug that is on the plan’s formulary or complies with the utilization management requirements. See Appendix B for a description of how dual-eligible nursing home residents commonly obtain Part D drugs.

**Table 1: Nursing home administrators’ responses about residents’ receipt of Part D drugs**

	Administrators
Dual-eligible residents are receiving all Part D drugs	93%
Dual-eligible residents are not receiving all Part D drugs	4%
Don’t know	3%

Source: OIG analysis of interview data, 2007.

About 4 percent of administrators reported that at least one dual-eligible resident in each of their nursing homes is not receiving needed Part D drugs from their Part D plans or any other sources. Administrators estimated that a total of 23 residents, or an average of 4 residents in each of these nursing homes, had not received all necessary Part D drugs since the implementation of Part D. They

explained that some of these residents changed their Part D plans or were transferred to hospitals to receive the drugs they needed; others went without the drugs entirely.

As shown in Table 2, the majority of medical directors and pharmacy directors whom we interviewed also reported

**Table 2: Medical directors’ and pharmacy directors’ responses about residents’ receipt of Part D drugs**

	Medical Directors	Pharmacy Directors
Dual-eligible residents are receiving all Part D drugs	73%	84%
Dual-eligible residents are not receiving all Part D drugs	5%	4%
Don’t know	21%	13%

\*Note: The responses of the medical directors and pharmacy directors are not projectable to the population. Additionally, totals may not equal 100% because of rounding.  
Source: OIG analysis of interview data, 2007.

<sup>32</sup> For the purposes of this study, Part D drugs include all drugs that are eligible for coverage under Part D.

that dual-eligible nursing home residents are receiving all necessary Part D drugs. Specifically, 73 percent (69 of 95) of medical directors and 84 percent (66 of 79) of pharmacy directors reported that dual-eligible residents in the sampled nursing homes are receiving all necessary Part D drugs. However, 5 percent (5 of 95) of medical directors and 4 percent (3 of 79) of pharmacy directors reported that at least one resident went without necessary Part D drugs.

**Nursing homes and long-term care pharmacies sometimes pay for Part D drugs that are not covered by plans**

Nursing home administrators and pharmacy directors reported that they sometimes pay for Part D drugs that are not covered by plans. In total,

45 percent of administrators reported that their nursing homes paid for at least one Part D drug for dual-eligible residents. As several administrators explained, nursing homes may pay for these Part D drugs to comply with Federal regulations and Conditions of Participation that require nursing homes to ensure that residents receive needed drugs in a timely manner.<sup>33</sup> Additionally, 77 percent (61 of 79) of the pharmacy directors whom we interviewed reported that their pharmacies paid for at least one Part D drug for dual-eligible residents in the sampled nursing homes.

According to interviews with administrators and pharmacy directors, the drugs that they most commonly pay for either are not on the residents' plans' formularies or require prior authorization. For example, they may pay for a drug if the resident's physician determines that there is no alternative drug on the formulary appropriate for the resident.<sup>34</sup> They may also pay for a short-term supply of drugs during the prior authorization process. Several pharmacy directors explained that not all plans cover the cost of a short-term supply of drugs during the prior authorization process and, as a result, the nursing home or pharmacy may pay for these drugs during this time.

Several respondents noted that paying for Part D drugs is causing a financial strain on their nursing homes. For example, one

<sup>33</sup> 42 CFR § 483.60; 42 CFR Part 483; see also CMS, "State Operations Manual, Appendix PP—Guidance to Surveyors for Long-Term Care Facilities," p. 442.

<sup>34</sup> Medicare beneficiaries can request exceptions when their physicians prescribe drugs that are not on their plans' formularies. However, only a few administrators specifically noted that residents had requested exceptions.

administrator stated that her nursing home budgets \$10,000 per month for nonreimbursed drug costs. According to one medical director, the cost of these drugs may affect nursing home admissions practices because the nursing home may not admit patients if it cannot afford their medication.

**Respondents express concerns that formularies, the prior authorization process, and copayments may pose problems for dual-eligible nursing home residents**

Nursing home administrators as well as the medical directors and pharmacy directors whom we interviewed expressed several concerns about Part D that are specific to dual-eligible nursing

home residents. In general, they have concerns about plan formularies, prior authorization, and residents being incorrectly identified as required to pay copayments.

**Respondents are concerned that formularies can be problematic for dual-eligible residents in nursing homes**

About one-fifth of nursing home administrators are concerned that plan formularies may not meet all of the needs of some dual-eligible nursing home residents. A similar proportion of medical directors and pharmacy directors whom we interviewed also reported concerns about plan formularies. Several medical directors specifically noted that the therapeutically equivalent drugs on the formulary are not always appropriate for residents because they may cause adverse side effects or may not be in the proper form. As one pharmacy director noted, the therapeutically equivalent drugs on one plan’s formulary cannot be administered via a feeding tube.

Administrators and pharmacy directors further noted that plans do not always cover injectable anemia drugs, oral cancer drugs, and drugs administered by nebulizers. In general, these drugs can be covered by either Part D or Part B depending on the circumstances. For example, Part D covers drugs administered by nebulizers for beneficiaries in nursing homes, whereas Medicare Part B covers these drugs for beneficiaries who are at home.<sup>35</sup> One pharmacy director noted that

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<sup>35</sup> Medicare Part D only covers drugs that are not covered by Medicare Part B. See 42 U.S.C. § 1395w-102(e)(2)(B); see also CMS, “Prescription Drug Benefit Manual: Chapter 6—Part D Drugs and Formulary Requirements,” Appendix C-1 and C-2. Available online at [http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts\\_03.09.07.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts_03.09.07.pdf). Accessed on November 7, 2007.

## F I N D I N G S

some plans will not cover injectable drugs because the plans are not aware that the drugs are eligible for coverage under Part D for nursing home residents. One administrator explained that some plans are confused about whether these drugs should be covered under Part B or Part D.

A number of medical directors were also concerned about how formulary restrictions may affect residents' quality of care. As one medical director explained, although a resident may receive a drug, it may not always be the most effective drug. Others expressed concerns that switching drugs may increase medical errors or cause more negative health effects in the future, such as heart attacks and strokes.

### **Respondents are concerned that the prior authorization process can be particularly burdensome in the nursing home setting**

About one-fifth of nursing home administrators expressed concerns that the prior authorization process can be burdensome. A similar proportion of the medical directors and pharmacy directors whom we interviewed also reported such concerns. Respondents commonly pointed out the amount of time they spend handling prior authorizations. Several explained that prior authorization forms and procedures vary across plans, which is particularly difficult because nursing homes have residents enrolled in many different plans. According to administrators, a typical nursing home works with an average of 10 different plans.

Several pharmacy directors further noted that the prior authorization process may be lengthy because of problems with plans. They reported experiencing long wait times before being able to speak with plan staff. They also noted that plan staff sometimes lack sufficient knowledge of formulary and coverage issues specific to nursing home residents.

A number of medical directors also stated that the burdensome nature of the process can affect patient care. For example, as one noted, the time nursing home staff and physicians spend on the prior authorization process reduces the time they can spend providing patient care. Additionally, as another medical director stated, to avoid dealing with the prior authorization process, some physicians may just switch to any drug in the category. Another medical director pointed out that the process can be too lengthy and patients may suffer because of delays in receiving drugs.

### **Dual-eligible nursing home residents are being incorrectly identified as required to pay copayments**

Dual-eligible beneficiaries residing in nursing homes are eligible to have their premiums, deductibles, and copayments fully subsidized for prescription drugs covered under Part D.<sup>36</sup> CMS issued a memorandum in May 2006 clarifying that dual-eligible residents should not be charged copayments if they reside in nursing homes for at least 30 days and are under a covered Medicaid stay.<sup>37</sup> The memorandum also outlined steps to address the issue, including instructing plans to use “best available data” when they have knowledge that a beneficiary’s cost-sharing level is not correct.<sup>38</sup> It further directed plans to repay long-term care pharmacies for these copayments rather than beneficiaries because it is unlikely that the long-term care pharmacies have billed the beneficiaries for their copayments.<sup>39</sup>

Despite the issuance of this memorandum, dual-eligible residents continue to be incorrectly identified as required to pay copayments. In fact, 80 percent (63 of 79) of the pharmacy directors whom we interviewed reported that dual-eligible nursing home residents were incorrectly identified by their plan as required to pay copayments in the last 3 months of 2006. Additionally, several pharmacy directors reported having large amounts of uncollected copayments. For example, one pharmacy director had approximately \$300,000 in uncollected copayments. Another pharmacy director reported having over \$75,000 in uncollected copayments in the past year.

Pharmacy directors explained that for a plan to assess zero copayments for these beneficiaries, it must recognize that these individuals are dual eligible and that they reside in nursing homes. About half of the pharmacy directors who offered an explanation reported that residents are not being properly identified as dual eligible. The other half of pharmacy directors reported that residents are not being properly identified as residing in nursing homes.

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<sup>36</sup> 42 CFR § 423.782. According to CMS, “[a]n individual is considered institutionalized and qualifies for a zero co-payment when he or she is a full benefit dual-eligible, a resident of a long-term care facility for a full calendar month, and under a covered Medicaid stay.”

<sup>37</sup> CMS, “Incorrect Cost Sharing Charges to Dual-Eligible Beneficiaries” (May 5, 2006).

<sup>38</sup> For example, if a plan has knowledge from the nursing home that the beneficiary’s nursing home stay is covered by Medicaid, the plan should revise the copayment level. See *ibid.*

<sup>39</sup> CMS, “Incorrect Cost Sharing Charges to Dual-Eligible Beneficiaries” (May 5, 2006).

**Concerns also exist that long-term care pharmacies generally do not disclose to physicians the rebates they receive from drug manufacturers**

According to our interviews, long-term care pharmacies have continued to receive rebates from drug manufacturers under Part D and they generally do not disclose these rebates to physicians. In total,

54 percent (43 of 79) of the pharmacy directors whom we interviewed reported that their pharmacy receives rebates from drug manufacturers either directly or through group purchasing organizations.<sup>40</sup> These directors explained that rebates are often based on market share or volume. For example, one pharmacist, who receives rebates based on market share, explained that his rebates are based on the percentage he dispenses of a particular drug, compared to the percentage he dispenses of the competitor's drug. Another pharmacy director explained that if 90 percent or more of the insulin she sells is from a certain manufacturer, she receives a 1-percent rebate.

Physicians may not be aware that pharmacies receive these rebates. Only three of the pharmacy directors we interviewed reported that their pharmacies provided information to nursing homes or to physicians about the rebates that they receive.<sup>41</sup>

Rebates are a concern because pharmacists employed by these long-term care pharmacies can influence the drugs that are prescribed to residents when drugs are initially ordered. According to the nursing home administrators, when a physician orders a drug that is not on the formulary, the pharmacist commonly suggests one or two alternative drugs from a longer list of drugs on the formulary. The physicians typically follow the suggestions of the pharmacists. Specifically, the medical directors whom we interviewed reported that they make the pharmacists' recommended changes about 78 percent of the time.

In addition, pharmacists can influence the drugs that are prescribed during the drug regimen reviews. As described earlier, nursing homes are

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<sup>40</sup> A group purchasing organization is an entity that uses collective buying power to obtain discounts from vendors.

<sup>41</sup> Long-term care pharmacies are required to report the rebates that they receive to plans; however, they are not required to provide this information to nursing homes or physicians. See Medicare Part D Reporting Requirements Contract Year 2008.

Available online at [http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements\\_NextYear.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements_NextYear.pdf). Accessed on August 10, 2007.

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required to have a consultant pharmacist review the drug regimens of all residents at least monthly. About 80 percent of the nursing home administrators reported that the consultant pharmacists who perform their drug regimen reviews are employees of the long-term care pharmacy that provide Part D drugs to their residents. During these reviews, consultant pharmacists can make recommendations to change residents' drugs. The medical directors whom we interviewed reported that when consultant pharmacists recommend changing one drug for a different, therapeutically equivalent drug, they make these changes about 74 percent of the time.

Taken together, these issues raise concerns that rebates may create incentives for pharmacists and consultant pharmacists to recommend certain drugs over others based on financial considerations as opposed to clinical considerations and that physicians may not be aware of these incentives when deciding whether to take pharmacists' recommendations.

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According to most respondents, dual-eligible nursing home residents are receiving all necessary Part D drugs. This is due, in part, to nursing homes and long-term care pharmacies paying for some drugs that plans do not cover. In addition, respondents raised several concerns about Part D that are specific to dual-eligible nursing home residents including concerns about plan formularies, the prior authorization process, and copayments. We are also concerned that long-term care pharmacies receive rebates from drug manufacturers which create financial incentives to recommend certain drugs and that they do not generally disclose these incentives to physicians. Based on these findings, we plan to do additional work on long-term care pharmacy rebates. In addition, we recommend that CMS take the following actions:

**Work With Plans To Ensure That Formularies Meet the Needs of Dual-Eligible Nursing Home Residents**

CMS should work with plans to ensure that the drug needs of dual-eligible nursing home residents are taken into consideration. CMS reviews each plan's formulary to ensure that it provides access to appropriate treatments for all diseases and is not designed to discourage enrollment by any particular group. During this review process, CMS should put additional emphasis on ensuring that plans include the drugs and alternative dosages and forms that meet the needs of dual-eligible nursing home residents. In addition, we recognize that CMS has issued guidance explaining when drugs should be covered by Part B or Part D. CMS should work with plans to ensure that dual-eligible residents do not have difficulty obtaining drugs under Part D that may be covered by Part B in other circumstances or patient settings.

**Continue To Work With Plans To Improve the Prior Authorization Process**

We recognize that CMS issued new transition guidance for 2007 requiring plans to provide up to a 90-day supply of nonformulary drugs and drugs requiring prior authorization or step therapy prescribed for newly enrolled nursing home residents and up to a 31-day supply of such drugs for current enrollees while an exception is being processed. CMS should clarify existing guidance to ensure that plans pay for a supply of drugs for current enrollees during routine prior authorization



## R E C O M M E N D A T I O N S

requests. Further, CMS should specify under what circumstances a supply of drugs would qualify as being an emergency supply. In addition, CMS should work with plans to ensure that plan staff are responsive and knowledgeable about Part D formulary and coverage issues that are specific to dual-eligible nursing home residents. Further, CMS should consider working with partners, such as the American Medical Association, to educate physicians about using the standardized form and about the transition policy.

### **Ensure That Copayments for Dual-Eligible Nursing Homes Residents Are Fully Subsidized, as Appropriate**

CMS should continue its efforts to ensure that residents are properly identified as dually eligible and as residing in a nursing home. CMS should also work with plans to ensure they are using “best available data” when they have knowledge that a beneficiary is being inappropriately charged copayments. CMS should also consider educating long-term care pharmacies and nursing homes about what “best available data” they can provide to plans.

### **Consider Methods To Encourage Long-Term Care Pharmacies To Disclose to Physicians Information About Rebates That They Receive From Drug Manufacturers**

We recognize that CMS does not have the authority under Part D to require long-term care pharmacies to disclose to physicians the rebates that they receive from drug manufacturers. However, CMS can consider methods to encourage long-term care pharmacies to disclose to physicians information about their rebates. Because long-term care pharmacists can influence the drugs that are prescribed to residents in nursing homes, it is important that physicians be aware of any potential financial incentives that pharmacists may have to recommend one drug over another.

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## **AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In its comments on the draft report, CMS agreed that our review identifies potential issues with ensuring that dual-eligible nursing home residents are receiving all necessary Part D drugs and that further work is needed in the areas highlighted by the report. In addition, CMS concurred with our first two recommendations and the intent of the third recommendation; it did not concur with the last recommendation.

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CMS concurred with our first recommendation that it work with plans to ensure that formularies meet the needs of dual-eligible nursing home residents. CMS stated that it believes it substantially does this but will look for opportunities to improve. It will continue to work with its partners and monitor complaints regarding formularies and will adjust the formulary review process as necessary. It will also consider our recommendations as it constructs the formulary review checks for calendar year 2009 formularies.

CMS concurred with our second recommendation to continue to work with plans to improve the prior authorization process. CMS noted that it issued a memorandum to Part D sponsors directing them to make plan prior authorization criteria available upon request of the beneficiary or physicians. CMS also stated that it would update its guidance in the next revision of Chapter 6 of the “Part D Manual” and ensure that long-term care beneficiaries have access to an emergency supply of drugs anytime during the plan year. Further, as CMS continues to work with long-term care partners and providers, it will emphasize protections available to long-term care beneficiaries, including the model coverage determination form, Part D plans’ transition processes, and emergency supplies.

Although CMS concurred with the intent of our third recommendation to ensure that copayments for dual-eligible nursing home residents are fully subsidized, as appropriate, it expressed concern over the use of the term “waive” in the report. CMS requested that OIG not use “waive” in the context of Part D payments because, among other reasons, it may confuse the public because CMS describes payment and nonpayment of cost-sharing liability under Part D in a specific manner and also because waiving copayments would be a violation of Federal law. In response to CMS’s concerns over the potential for confusion, we modified the language of the report. We note, however, that Federal laws are not automatically violated if copayments are waived; rather, Federal laws may be implicated when providers, practitioners, and suppliers waive copayments for services or products and could ultimately result in criminal, civil, or administrative liability.

In addition, in response to our third recommendation, CMS explained that currently it reports beneficiary copayment levels to Part D sponsors on a weekly basis, while States submit information to CMS on beneficiary dual eligibility and institutional status on a monthly basis. CMS stated that it is working to increase the frequency of State

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reporting and its processing of these data. In addition, CMS stated that it has already taken a number of steps relative to its best available evidence policy. It posted a document to the CMS Pharmacy Listserv on the topic and established a separate complaint-tracking category for “best available evidence” issues. It also plans to release two tip sheets.

CMS did not concur with our fourth recommendation to consider methods to encourage long-term care pharmacies to disclose to physicians information about rebates that they receive from drug manufacturers. CMS stated that it does not have authority under Part D to require long-term care pharmacies to disclose their rebates to physicians. CMS noted that to ensure that the rebates received by long-term care pharmacies do not create incentives that are contrary to a Part D plan’s formulary, it currently requires Part D sponsors to collect and review information regarding rebates received by their network long-term care pharmacies. We recognize that CMS does not have the authority to require pharmacies to disclose their rebates to physicians. However, we continue to recommend that CMS consider additional ways to encourage pharmacies to disclose this information to physicians so that they are aware of any potential financial incentives that pharmacists may have to recommend one drug over another.

CMS also commented on the findings. In response to our first finding, CMS requested that we recalculate the data to exclude respondents who reported that they did not know whether residents received needed drugs. We included these responses in our analysis to ensure we present the data in a complete and unbiased manner. In response to our second finding, CMS agreed to issue clarified guidance. CMS noted that although the intent of the existing guidance was to cover nonformulary drugs during transition periods, it could issue clarified guidance.

CMS made several comments related to our methodology. Specifically, CMS stated that it believes it is a serious omission that we did not interview consultant pharmacists because they operate independently of long-term care pharmacy directors in influencing drugs. As we noted in the report, about 80 percent of the nursing home administrators reported that the consultant pharmacists who perform their drug regimen reviews are employees of the long-term care pharmacy that provides Part D drugs to their residents.

We made several technical changes based on CMS’s comments. The full text of CMS’s comments is included in Appendix C.

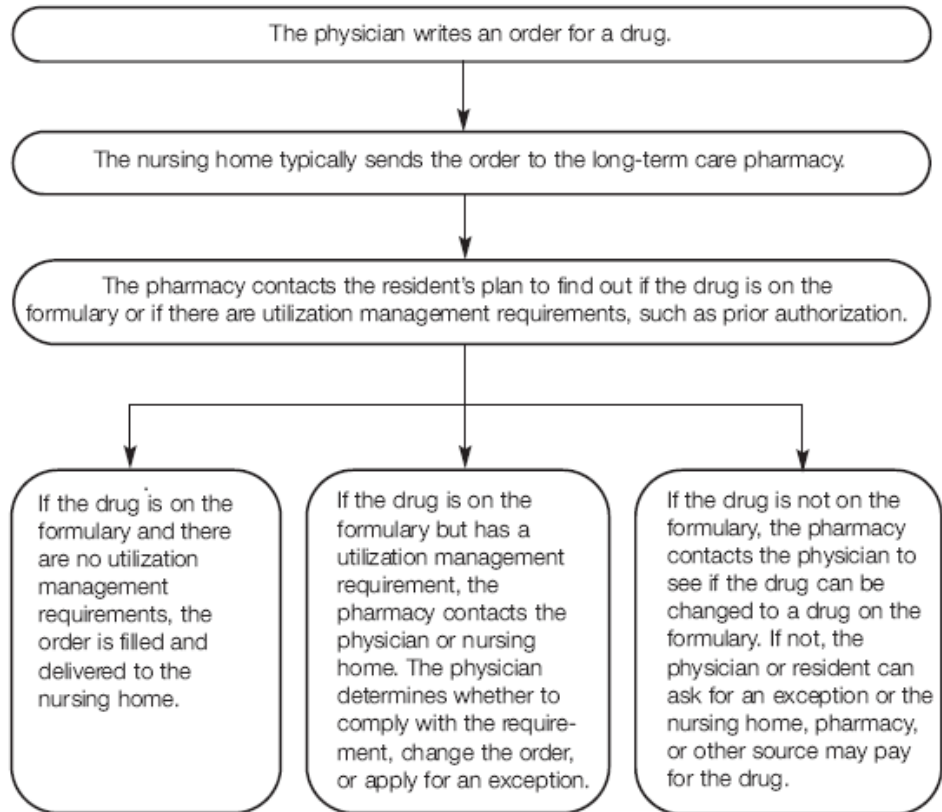
➤ A P P E N D I X ~ A

Confidence Intervals for Selected Estimates for Nursing Home Administrators  
(Sample Size = 128)

Estimate Description	Point Estimate	95-Percent Confidence Interval
Percentage of nursing home administrators who reported that dual-eligible residents in their nursing home are receiving all necessary Part D drugs	92.9%	88.5%–97.3%
Percentage of nursing home administrators who reported that dual-eligible residents are not receiving all necessary Part D drugs	3.9%	0.5%–7.3%
Percentage of nursing home administrators who reported that they “do not know” whether dual-eligible residents are receiving all necessary Part D drugs	3.1%	0.1%–6.1%
Percentage of nursing home administrators who reported that their nursing homes paid for at least one Part D drug for dual-eligible residents	44.5%	35.9%–53.1%
Percentage of nursing home administrators who are concerned about plan formularies may not meet all of the needs of some dual-eligible nursing home residents	20.0%	13.1%–26.9%
Percentage of nursing home administrators who expressed concerns that the prior authorization process can be burdensome	18.0%	11.3%–24.7%

➤ A P P E N D I X ~ B


**Common  
Process for  
Obtaining  
Drugs for  
Dual-Eligible  
Nursing Home  
Residents  
Under Part D**



Source: Office of Inspector General analysis of interview responses, 2007.

▶ APPENDIX - C

Agency Comments

 DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
Office of the Administrator  
Washington, DC 20201

DATE: APR 11 2008

TO: Daniel R. Levinson  
Inspector General

FROM: Kerry Weems  
Acting Administrator *Kerry Weems*

SUBJECT: Office of Inspector General (OIG) Draft Report: "Availability of Medicare Part D Drugs to Dual-Eligible Nursing Home Residents" (OEI-02-06-00190)

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OFFICE GENERAL

Thank you for the opportunity to review and comment on the OIG draft report to assess the availability of Medicare Part D drugs to dual-eligible nursing home residents. We agree that this review by the OIG identifies potential issues with ensuring that dual-eligible nursing home residents are receiving all necessary Part D drugs and that further work is needed to ensure that plan formularies, the prior authorization process, and copayments do not pose problems for dual-eligible nursing home residents.

Methodology

In the Limitations subsection, the OIG acknowledges that interviews were not conducted with consultant pharmacists. We believe this is a serious omission, since their input could significantly alter the study findings. Consultant pharmacists operate independently of nursing home pharmacy directors in influencing the drugs received by residents through their drug regimen reviews and, therefore, are essential to an assessment of nursing home medications.

OIG Finding

The OIG found that most respondents reported that dual-eligible nursing home residents are receiving all necessary Part D drugs.

CMS Response

While CMS is pleased that most respondents reported that dual-eligible residents received necessary drugs, the report goes on to report that a significant number of respondents did not know about the receipt of drugs. Thus, we believe this finding is misleading. The report states that 93 percent of nursing home administrators, 73 percent of medical directors, and 84 percent of pharmacy directors reported that dual-eligible nursing home residents are receiving all necessary Part D drugs. However, a significant number of respondents in the latter groups reported they did not know about residents' receipt of Part D drugs. We believe, therefore, all

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respondents who reported they did not know should be excluded from the analysis and these numbers should be recalculated. Furthermore, it is uncertain whether the respondents appropriately distinguished among payers, their formularies, and prior authorization processes in responding to the survey questions.

OIG Finding

The OIG found that nursing homes and long-term care pharmacies sometimes pay for Part D drugs that are not covered by plans.

CMS Response

We agree to issue clarified guidance as a result of this finding. The report states that, according to respondents, the drugs nursing homes most commonly pay for either are not on the plans' formularies or require prior authorization. CMS issued guidance to Part D sponsors on May 25, 2007, entitled "Special Transition Period for Retroactive Enrollment," requiring sponsors to accommodate claims from beneficiaries and other parties, which would include long-term care pharmacies and long-term care facilities, who made payment for a covered Part D drug during a retroactive period covered under a special transition period. This policy includes claims for non-formulary Part D drugs during a no-greater-than 7-month period of retroactive eligibility. While the intent of our policy guidance is to require sponsors to reimburse these claims, we agree we could issue clarified guidance targeted at nursing homes so the administrators are aware of this policy.

OIG Recommendation

The OIG recommends that CMS work with plans to ensure that formularies meet the needs of dual-eligible nursing home residents.

CMS Response

We concur with this recommendation and believe we substantially do this, but will look for all opportunities to improve. CMS' formulary review process currently includes checks that help ensure dual-eligible nursing home residents have access to medically necessary drugs and dosage forms. This review is not limited to the drug list alone. The specific dosage forms of these drugs that meet the unique needs of long-term care residents are also required on formularies (e.g., liquids and orally disintegrating tablets). For calendar years 2007 and 2008, CMS incorporated the list of most commonly utilized drugs by the dually eligible Medicare population (as identified in the OIG's report: *Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs*) into its review process. In addition, CMS reviewed formularies for the inclusion of "all or substantially all" drugs from the six classes of clinical concern (antidepressants, antipsychotics, anticonvulsants, antiretrovirals, immunosuppressants, and antineoplastics).

As CMS continues to evaluate its formulary review process, new information will continue to be considered. We continue to work with our partners and monitor complaints regarding Part D formularies and will adjust the formulary review process as this surveillance necessitates. CMS

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will also consider OIG's recommendations as it constructs the formulary review checks for the calendar year 2009 formularies.

OIG Recommendation

The OIG recommends that CMS continue to work with plans to improve the prior authorization process.

CMS Response

We concur with this recommendation. CMS already has worked to improve the transparency related to Part D plan prior authorization processes and requirements. In a June 14, 2007, memorandum to Part D sponsors, CMS directed Part D sponsors to make plan prior authorization criteria available upon request of the beneficiary or their physicians. Further, CMS has announced that sponsors will use a standardized document to submit prior authorization criteria as part of the CMS 2009 formulary review.

However, CMS believes we can further improve our guidance on the provision of an emergency supply in a long-term care setting during routine prior authorization. Current guidance contained in Chapter 6 of the Medicare Prescription Drug Manual, section 30.4.4, states that Part D plans must provide an emergency supply of a non-formulary Part D drug – including Part D drugs that are on a plan's formulary but require prior authorization – while an exception is being processed. The intent of the original guidance supported general practice in the long-term care setting where ordered drugs are provided without delay, regardless of formulary status or drug utilization management tools. While this guidance requires Part D plan sponsors to provide up to a 31-day supply when an exception is actually filed with the plan, it does not specifically direct the sponsor to provide a supply during the period of time the beneficiary or physician collects the information necessary to substantiate the prior authorization. However, denying access to necessary medication for any period of time is not the standard of practice in long-term care facilities and is not in line with our original intent. As a result, CMS will update the guidance in the next revision of Chapter 6 of the Part D Manual and ensure that long-term care beneficiaries have access to an emergency supply anytime during the plan year.

With regard to ongoing educational efforts, CMS continues to work with long-term care partners and providers to assess and address issues related to the Part D program. Within the context of these ongoing conversations, we will emphasize beneficiary protections available to long-term care beneficiaries, including the availability of a model coverage determination form, Part D plans' transition processes, and emergency supplies. CMS will also continue to work with Part D sponsors through Part D User Calls and Health Plan Management System memoranda, when necessary, to ensure that long-term care beneficiaries receive the benefits they deserve under the Part D program.

OIG Recommendation

The OIG recommends that CMS ensure that dual-eligible nursing home residents' copayments are waived, as appropriate.



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CMS Response

While we concur with the OIG's intent, we strongly request this recommendation be rewritten. Copayments for dual-eligible nursing home residents are not "waived" (which would be a violation of Federal law), but rather are fully subsidized by CMS. Although the OIG uses "waiver" as synonymous with "eliminate," the term "waiver" as applied to cost-sharing has a precise meaning in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Specifically, section 101(e) of the MMA added subparagraph (G) to the anti-kickback statute at section 1128B(b)(3) of the Social Security Act, which permits pharmacies (as opposed to Part D sponsors), under specified conditions, to waive or reduce cost-sharing. However, our concerns over the choice of terminology extend beyond the anti-kickback issue; there are potential issues related to inducement, Medicare Parts C and D bid validity, and uniform benefits involved as well.

The CMS must respond to many questions concerning the payment and non-payment of cost sharing, and how we describe the basis for our policy is material to how it is interpreted and applied. The cost-sharing for institutionalized dual-eligible beneficiaries is fully subsidized by CMS, not waived. This distinction is meaningful to CMS, and we believe the use of imprecise language in a public record may serve to confuse the public discourse. Therefore, in addition to rewriting the recommendation, we strongly request the language on page 2 of the report wherein the OIG defines its use of the word "waive" be revised as well.

Currently, CMS reports beneficiary copayment levels to Part D sponsors on a weekly basis. States submit updated information on beneficiary dual eligibility and institutional status on monthly files to CMS. After all State files are received, CMS communicates the updated information to the Part D sponsors. CMS is working to increase the frequency of this State reporting to CMS as well as the frequency of our processing of these data to improve the timeliness of the availability of this information for accurate claims adjudication by Part D sponsors.

Since the OIG completed the interviews for this study, CMS has already taken a number of important steps relative to our best available evidence policy to ensure low-income subsidy eligible individuals are identified and charged the appropriate copayment. On June 27, 2007, CMS issued guidance to Part D sponsors entitled "Low-Income Subsidy (LIS) Status Corrections Based on Best Available Evidence." This guidance reiterated our requirement that Part D sponsors accept and use the specified forms of best available evidence to document a beneficiary's correct LIS status and to change the beneficiary's cost-sharing levels in the sponsor's system. In addition, the guidance directed sponsors to submit to CMS requests for correction of these data in our system, if routine monthly reporting from the State does not correct the CMS data.

Further, on November 1, 2007, we posted a two-page document to the CMS Pharmacy List Serve, reminding all pharmacies of the best available evidence policy and our guidance to Part D sponsors. Also, given the importance of this policy, we have established a separate complaint tracking category for "best available evidence" issues and will be closely monitoring Part D sponsor compliance with this policy.

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Additionally, two tip sheets on the CMS best available evidence policy and guidance to plan sponsors are currently being finalized. One of these sheets is targeted to Medicare beneficiaries, the other to our Part D partners, including nursing homes and long-term care pharmacies. We are planning to release these documents shortly.

OIG Recommendation

The OIG recommends CMS consider methods to encourage long-term care pharmacies to disclose to physicians information about rebates that they receive from drug manufacturers.

CMS Response

We do not concur with this recommendation. CMS understands and appreciates the concern that rebates may create incentives for pharmacists to recommend certain drugs for residents based on financial considerations as opposed to clinical considerations. However, since CMS does not have the authority under Part D to require long-term care pharmacies to disclose their rebates to physicians, we strongly suggest this recommendation be eliminated.

For the Medicare Part D program, CMS contracts directly with health insurance providers and does not contract with the pharmacies. However, to ensure that the rebates received by long-term care pharmacies do not create incentives that are contrary to a Part D plan's formulary, we currently require Part D sponsors to collect and review information regarding rebates received by their network long-term care pharmacies.

Other Comments

1. In the Findings section on pages 9 and 10, the report switches between the terms “needed drugs” and “all necessary Part D drugs.” We presume that the discussion is always related to Part D drugs and excluded drugs were not included in the analysis; however, as the report is written, this is not always clear.
2. Further, while the OIG understands the excluded categories of drugs, there are no assurances that the respondents understand that a number of drugs are specifically excluded from the Part D program. Facility payment for commonly used excluded drugs may have affected their answers and biased the results, and we recommend a caveat to this effect be incorporated in the report.
3. Part D has likely affected the profitability of long-term care pharmacies due to lower reimbursement for drugs. Factors such as reimbursement rates and long-term care pharmacy complaints may have influenced the respondents’ answers. Recognition of this potential bias should be reflected in the report.
4. The data upon which the report’s findings and recommendations are based are derived from interviews conducted between September 2006 and March 2007 and should be placed in the proper context as a snapshot at one point in time almost a year ago. This is

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particularly evident in the discussion about the report's findings that dual-eligible nursing home residents are being incorrectly identified as having to pay copayments, which begins on page 13. Here, the report states that "...80 percent (63 of 79) of the pharmacy directors interviewed reported that dual-eligible nursing home residents were incorrectly identified by their plan as required to pay copayments in the last 3 months of 2006." The report should more openly acknowledge the fact that these interviews were conducted some time ago, those interviewees' experiences could have also changed since that time, as the program has developed, and CMS has been making improvements to our processes.

We appreciate the effort that went into this report. Again, we thank you for the opportunity to review and comment.



## A C K N O W L E D G M E N T S

This report was prepared under the direction of Jodi Nudelman, Regional Inspector General for Evaluation and Inspections in the New York regional office, and Meridith Seife, Deputy Regional Inspector General.

Miriam Anderson served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the New York regional office who contributed to this report include Taryn Eckstein and David Rudich. Other regional and central office staff who contributed include Kevin Farber, Vincent Greiber, Jennifer Jones, Sandy Khoury, Christine Moundas, and Michelle McInnis.