

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**COMPARING SPECIAL NEEDS  
PLAN BENEFICIARIES TO OTHER  
MEDICARE ADVANTAGE  
PRESCRIPTION DRUG PLAN  
BENEFICIARIES**



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# *Office of Inspector General*

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## E X E C U T I V E S U M M A R Y

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### OBJECTIVE

To compare Special Needs Plan (SNP) beneficiaries to other Medicare Advantage Prescription Drug Plan (MA-PD) beneficiaries regarding drug utilization, drug costs, and exposure to potentially inappropriate drug pairs.

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### BACKGROUND

Congress created the SNP authority to allow Medicare managed care, known as Medicare Advantage (MA) plans, to develop targeted clinical programs to care more effectively for high-risk beneficiaries. Among other services, SNPs offer prescription drug coverage. Any MA plan that offers Part D prescription drug coverage is known as an MA-PD.

Since SNPs became available in 2006, the number of SNPs and SNP beneficiary enrollment have grown rapidly. Policymakers have focused their attention on SNPs because of this growth and because SNPs, like other MA plans, cost more per beneficiary than fee-for-service Medicare. In particular, policymakers have questioned whether SNPs are providing specialized care for special needs individuals.

Because SNPs target special needs individuals who are more likely to have complicated medical regimens, SNP beneficiaries may have an increased risk of exposure to therapeutic duplications or drug-drug interactions. Therapeutic duplications occur when two drugs that treat the same medical condition, taken together, increase the risk of toxicity. Drug-drug interactions occur when two drugs taken together lead to increased toxicity or changes in the efficacy of one or both drugs.

Therapeutic duplications and drug-drug interactions may be prescribed or dispensed in error or may be part of a clinically appropriate drug regimen. Regardless, they have the potential to lead to an adverse drug event (ADE). An ADE may involve temporary or moderate side effects or can have serious consequences, including disability or death. Because therapeutic duplications and drug-drug interactions can lead to ADEs they may require monitoring or a change in drug regimen. Throughout the report, we refer to therapeutic duplications and drug-drug interactions, when aggregated, as potentially inappropriate drug pairs.

We used Medicare Part D prescription drug data to compare SNP beneficiaries to other MA-PD beneficiaries regarding drug utilization,

costs, and exposure to potentially inappropriate drug pairs during 2006. Prescription drug data are the only encounter-level data available for comparing SNP beneficiaries to other MA-PD beneficiaries.

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## FINDINGS

**On average, SNP beneficiaries had higher prescription drug utilization and costs than other MA-PD beneficiaries.** On average, SNP beneficiaries filled 11 percent more prescriptions than other MA-PD beneficiaries in 2006. In addition, the average annual prescription cost per SNP beneficiary was 49 percent higher compared to that of other MA-PD beneficiaries. The difference in average annual prescription drug cost per beneficiary between SNPs and other MA-PDs appears to be because of SNP beneficiaries' higher utilization, utilization of costlier drugs, lower utilization of less costly 90-day prescriptions, and SNPs paying more on average than MA-PDs for some highly utilized drugs.

**Despite SNP beneficiaries' higher rates of drug utilization, SNP and other MA-PD beneficiaries were similarly exposed to potentially inappropriate drug pairs.** Although SNP beneficiaries filled 11 percent more prescriptions than other MA-PD beneficiaries on average, the same percentage of both SNP and other MA-PD beneficiaries were exposed to potentially inappropriate drug pairs. In addition, at higher levels of drug utilization, SNP beneficiaries were less likely to be exposed to a potentially inappropriate drug pair than other MA-PD beneficiaries.

**The majority of potentially inappropriate drug pairs were drug-drug interactions of moderate risk for both SNP and other MA-PD beneficiaries.** The frequency and severity of potentially inappropriate drug pairs were similar for SNP and other MA-PD beneficiaries during 2006. Sixty-five percent of potentially inappropriate drug pairs for both SNP and other MA-PD beneficiaries were drug-drug interactions, 83 percent of which were of moderate risk. In addition, the majority of potentially inappropriate drug pairs for both SNP and other MA-PD beneficiaries recurred and involved drugs prescribed by the same physician and filled by the same pharmacy.

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## RECOMMENDATION

**The Centers for Medicare & Medicaid Services should help SNPs and other MA-PDs provide physicians and pharmacists the information they need to prevent inappropriate drug pairs leading to ADEs.** The number of potentially inappropriate drug pairs prescribed and dispensed to Medicare beneficiaries could be reduced if physicians and pharmacists have access to accurate and targeted information regarding inappropriate drug pairs for the Medicare population. The Centers for Medicare & Medicaid Services (CMS) should continue to encourage plans to fully implement an e-prescribing program that improves information physicians and pharmacists have about beneficiaries' medication histories. In addition, CMS should provide plans information on inappropriate drug pairs most likely to lead to severe or serious ADEs in the Medicare population. Finally, CMS should encourage plans to provide tools to assist physicians and pharmacists in appropriately analyzing and using the information they receive.

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation to help SNPs and other MA-PDs provide physicians and pharmacists the information they need to prevent inappropriate drug pairs that could lead to ADEs. CMS noted that Part D sponsors are currently required to maintain systems to monitor drug utilization, including the use of potentially inappropriate drug pairs.

In addition, CMS expressed concern about our use of the First Databank drug product information database to identify potentially inappropriate drug pairs. CMS stated that First Databank algorithms have not been specifically validated for use in the Medicare population. Although this may be true, First DataBank is widely used by pharmacists, researchers, and health care plans, including the Department of Veterans Affairs, State Medicaid programs, and Part D sponsors, to identify inappropriate drug pairs.



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## OBJECTIVE

To compare Special Needs Plan (SNP) beneficiaries to other Medicare Advantage Prescription Drug Plan (MA-PD) beneficiaries regarding drug utilization, drug costs, and exposure to potentially inappropriate drug pairs.

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## BACKGROUND

Since Special Needs Plans (SNP) became available in 2006, the number of SNPs and SNP beneficiary enrollment have grown rapidly. Policymakers have focused their attention on SNPs because of this growth and because SNPs, like other Medicare managed care plans, cost the Federal Government more per beneficiary than fee-for-service Medicare. In particular, policymakers have questioned whether SNPs are providing specialized care for special needs individuals.<sup>1</sup> For these reasons, Congress placed a moratorium on the entry of new SNPs into Medicare from January 1, 2008, through December 31, 2009.<sup>2</sup> This moratorium provides additional time to study SNPs.

We used Medicare Part D prescription drug data to compare SNP beneficiaries to other MA-PD beneficiaries regarding drug utilization, costs, and exposure to potentially inappropriate drug pairs during 2006. Prescription drug data are the only encounter-level data available for comparing SNP beneficiaries to other MA-PD beneficiaries. Thus, the comparisons provided in this report offer insights into the population of beneficiaries enrolled in SNPs versus other MA-PD beneficiaries.

### Medicare Managed Care

Effective January 1, 2006, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA): (1) established the Medicare Advantage (MA) program to replace the Medicare + Choice program,<sup>3</sup> (2) added new MA plan types,<sup>4</sup> (3) changed MA payment

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<sup>1</sup> 153 Cong. Rec. S15834, 15835 (daily ed. Dec. 18, 2007) (Statement of Sen. Grassley).

<sup>2</sup> Medicare, Medicaid, and SCHIP Extension Act of 2007, P.L. No. 110-173 § 108, Social Security Act, § 1851 note, 42 U.S.C. § 1395w-21 note.

<sup>3</sup> MMA, P.L. No. 108-173 § 201, Social Security Act, § 1851 note, 42 U.S.C. § 1395w-21 note.

<sup>4</sup> MMA, P.L. No. 108-173 § 221, Social Security Act, § 1859(b), 42 U.S.C. § 1395w-28(b).

methodology,<sup>5</sup> and (4) provided qualified prescription drug coverage under Medicare Part D (Part D).<sup>6</sup>

### Special Needs Plans

Congress created the SNP authority to allow MA plans to develop targeted clinical programs to care more effectively for high-risk beneficiaries.<sup>7</sup> The SNP, a type of MA plan, may restrict enrollment to one or more classes of special needs individuals.<sup>8</sup> In contrast, all other MA plans are prohibited from restricting enrollment based on beneficiary health status.<sup>9</sup>

Special needs individuals are MA-eligible individuals who are:<sup>10</sup>

- institutionalized or require an equivalent level of care,<sup>11</sup>
- eligible for both Medicare and Medicaid (dual eligible), or
- suffering from a severe disability or have disabling chronic conditions and meet such other requirements as set by the Secretary.<sup>12</sup>

Congress initially authorized SNPs to target enrollment of special needs individuals through December 2008.<sup>13</sup> In 2008, Congress extended the SNP authorization through December 2010.<sup>14</sup> However, Congress also extended the moratorium on the designation of other MA plans as SNPs, originally in place through December 31, 2009, to December 31, 2010.<sup>15</sup>

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<sup>5</sup> MMA, P.L. No. 108-173 § 211, Social Security Act, § 1853(c)(1), 42 U.S.C. § 1395w-23(c)(1).

<sup>6</sup> MMA, P.L. No. 108-173 § 101, Social Security Act, § 1860D-1, 42 U.S.C. § 1395w-101.

<sup>7</sup> H.R. Rep. No. 108-391, at 555 (2003) (Conf. Rep.).

<sup>8</sup> Social Security Act, § 1859(f), 42 U.S.C. § 1395w-28(f).

<sup>9</sup> Social Security Act, § 1851(g), 42 U.S.C. § 1395w-21(g).

<sup>10</sup> MA-eligible individuals are both entitled to Medicare Part A and enrolled in Medicare Part B. Social Security Act, § 1851(a)(3), 42 U.S.C. § 1395w-21(a)(3).

<sup>11</sup> Centers for Medicare & Medicaid Services (CMS), “MA Special Needs Plan Guidance.” January 19, 2006. Available online at <http://www.cms.hhs.gov/SpecialNeedsPlans/Downloads/FinalSNPGuidance1-19-06R1.pdf>. Accessed on June 30, 2008.

<sup>12</sup> Social Security Act, § 1859(b)(6)(B), 42 U.S.C. § 1395w-28(b)(6)(B).

<sup>13</sup> MMA, P.L. No. 108-173 § 231, Social Security Act, § 1859(f), 42 U.S.C. § 1395w-28(f).

<sup>14</sup> Medicare Improvements for Patients and Providers Act of 2008, P.L. No. 110-275 § 164, Social Security Act, § 1859(f) note, 42 U.S.C. § 1395w-28(f).

<sup>15</sup> Medicare Improvements for Patients and Providers Act of 2008, P.L. No. 110-275 § 164, Social Security Act, § 1851 note, 42 U.S.C. § 1395w-21 note.



Before the moratorium, the number of SNPs and SNP beneficiary enrollment increased rapidly. In 2006, there were 276 SNPs.<sup>16</sup> By 2008, there were 769 SNPs.<sup>17</sup> Over this same period, SNP beneficiary enrollment increased over 102 percent. As of July 2008, over 1.2 million beneficiaries were enrolled in SNPs.<sup>18</sup>

In addition, SNPs, like other MA plans, continue to cost the Federal Government more per beneficiary than fee-for-service Medicare. The Medicare Payment Advisory Committee (MedPAC) has projected that SNPs will cost 15 percent more, and all MA plans 13 percent more, per beneficiary than fee-for-service Medicare in 2008.<sup>19</sup>

### **Prescription Drug Coverage by SNPs and Other MA-PDs**

MA plans that offer prescription drug coverage under Part D are referred to as MA-PDs.<sup>20</sup> All SNPs must offer prescription drug coverage and are therefore MA-PDs.<sup>21</sup> More than 8 million beneficiaries were enrolled in MA-PDs as of July 2008, including the over 1.2 million beneficiaries enrolled in SNPs.<sup>22</sup>

The Federal Government, through CMS, pays a portion of basic drug coverage through a monthly prospective direct subsidy payment to MA-PDs.<sup>23</sup> CMS adjusts MA-PD payments based on the estimated impact of enrollees' health on plans' costs using the Part D Hierarchical Condition Category risk adjustment model to calculate beneficiaries' Part D risk scores. The higher a beneficiary's risk score, the higher the payment is for that beneficiary.

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<sup>16</sup> CMS, "Special Needs Plans – Fact Sheet & Data Summary." Available online at <http://www.cms.hhs.gov/SpecialNeedsPlans/Downloads/FSNPFACt.pdf>. Accessed on March 27, 2008.

<sup>17</sup> CMS, "SNP Comprehensive Report," July 2008. Available online at <http://www.cms.hhs.gov/MCRAdvPartDnrolData/Downloads/SNP-200807.zip>. Accessed on July 28, 2008.

<sup>18</sup> Ibid.

<sup>19</sup> MedPAC, "Report to the Congress: Medicare Payment Policy March 2008," pp. 246–247. Available online at [http://www.medpac.gov/documents/Mar08\\_EntireReport.pdf](http://www.medpac.gov/documents/Mar08_EntireReport.pdf). Accessed on March 3, 2008.

<sup>20</sup> 42 CFR § 422.2.

<sup>21</sup> Ibid.

<sup>22</sup> CMS, "Monthly Contract and Enrollment Summary Report," July 2008. Available online at <http://www.cms.hhs.gov/MCRAdvPartDnrolData/Downloads/Contract%20Summary%20-%20July%202008.zip>. Accessed on July 28, 2008.

<sup>23</sup> 42 CFR § 423.329(a)(1).

Beneficiaries are typically responsible for paying a monthly premium, a deductible, and copayments for each prescription they fill.<sup>24</sup> However, beneficiaries with limited income and assets who meet certain requirements are eligible to receive assistance to pay for out-of-pocket costs associated with their prescription drug coverage.<sup>25</sup> Most SNP beneficiaries are dual eligibles (beneficiaries enrolled in both Medicare and Medicaid) who are automatically deemed eligible for this assistance.<sup>26 27</sup>

### **Therapeutic Duplication and Drug-Drug Interaction**

Therapeutic duplication occurs when the combined dose of two drugs from the same therapeutic class (i.e., groups of drugs that treat the same medical condition) increases the risk of toxicity. Drug-drug interaction occurs when two drugs taken together lead to a clinically significant toxicity or when one drug interferes with the effectiveness of the other.

Therapeutic duplication and drug-drug interaction may be the result of a medication error or may be part of a clinically appropriate drug regimen. Regardless, they have the potential to lead to an unexpected or dangerous reaction, called an adverse drug event (ADE). Thus, they may require monitoring or a change in drug regimen. Throughout the report, we refer to therapeutic duplication and drug-drug interaction, when aggregated, as potentially inappropriate drug pairs.

An ADE may involve temporary or moderate side effects such as nausea or a rash, or can have serious consequences including patient death or serious disabilities.<sup>28</sup> More severe ADEs could result in emergency department visits, hospital admissions, or death.<sup>29</sup> Among Medicare

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<sup>24</sup> Social Security Act, § 1860D-2, 42 U.S.C. § 1395w-102; and Social Security Act, § 1860D-13, 42 U.S.C. § 1395w-113.

<sup>25</sup> Social Security Act, § 1860D-14, 42 U.S.C. § 1395w-114.

<sup>26</sup> CMS, “SNP Comprehensive Report,” July 2008. Available online at <http://www.cms.hhs.gov/MCRAdvPartD/EnrolData/Downloads/SNP-200807.zip>. Accessed on July 28, 2008.

<sup>27</sup> Social Security Act, § 1860D-14, 42 U.S.C. § 1395w-114.

<sup>28</sup> Adverse Drug Events: Substantial Problem but Magnitude Uncertain: Hearing Before the U.S. Senate Committee on Health, Education, Labor, and Pensions, 106th Cong. 3 (2000) (Statement of Janet Heinrich, Associate Director for Health Financing and Public Health Issues, Health and Human Services Division, U.S. Government Accountability Office). Available online at <http://www.gao.gov/new.items/he00053t.pdf>. Accessed on March 27, 2008.

<sup>29</sup> Ibid.

enrollees, more than 1.9 million ADEs and more than 180,000 life-threatening or fatal ADEs occur each year. It is estimated that more than 25 percent of ADEs and 50 percent of life-threatening or fatal ADEs are preventable.<sup>30</sup>

SNP beneficiaries may be at an increased risk of potentially inappropriate drug pairs leading to ADEs. Age, severity of illness, and the number of prescribed drugs have been associated with a higher risk of ADEs.<sup>31</sup> SNP beneficiaries typically have chronic illnesses and multiple medical conditions that may require more drugs than other Medicare beneficiaries.<sup>32</sup>

### **Prescription Drug Safeguards and Safety Initiatives**

CMS requires all MA-PDs, including SNPs, to implement two safeguards designed, in part, to reduce ADEs and improve medication use: quality assurance systems and medication therapy management (MTM) programs.<sup>33</sup> In addition, CMS encourages e-prescribing as a means of preventing ADEs.<sup>34</sup> Finally, the Food and Drug Administration (FDA) is using Medicare Part D prescription drug data as part of the initiative to monitor drug safety.<sup>35</sup>

Quality assurance systems aim to protect beneficiaries, reduce ADEs, and improve medication use by reviewing beneficiaries' medications through concurrent and retrospective drug utilization review systems.

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<sup>30</sup> Jerry H. Gurwitz, et al., 2003. "Incidence and preventability of adverse drug events among older persons in the ambulatory setting." *Journal of the American Medical Association*, vol. 289(9), pp. 1107–1116.

<sup>31</sup> Agency for Healthcare Research and Quality, "Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs." Available online at <http://www.ahrq.gov/qual/aderia/aderia.htm>. Accessed on September 21, 2007.

<sup>32</sup> National Health Policy Group Memorandum, "Performance Measures for Special Needs Plans." Available online at <http://www.nhpg.org/media/3014/snpalliancesnppperformanceasures.pdf>. Accessed on October 9, 2007.

<sup>33</sup> 42 CFR §423.153.

<sup>34</sup> CMS, "E-Prescribing Tools To Help Prevent Adverse Drug Interactions Press Release," April 2, 2008. Available online at <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3025&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=false&choOrder=date>. Accessed on June 18, 2008.

<sup>35</sup> CMS, "New Efforts to Help Improve Medical Products for Patient Safety and Quality of Medical Care," May 22, 2008. Available online at <http://www.hhs.gov/news/press/2008pres/05/20080522a.html>. Accessed on August 27, 2008.

Concurrent drug utilization review systems screen for potential drug therapy problems at a drug's point of sale and alert pharmacists to potentially inappropriate drug pairs before the drugs have been dispensed to the patient. Retrospective drug utilization reviews are periodic examinations that may be used to identify potentially inappropriate drug pairs after the drugs have been dispensed.

MTM programs educate beneficiaries about the potential risks of their prescribed drug combinations.<sup>36</sup> At a minimum, a plan's MTM program must target enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed \$4,000.<sup>37</sup> Beyond these minimum standards, plans have significant flexibility in determining their targeted populations and designing the services their MTM programs provide and how they provide them.

In addition, CMS promotes the use of e-prescribing, anticipating that it will help reduce the number of ADEs for Medicare beneficiaries. Once e-prescribing is fully implemented, it has the potential to reduce ADEs by allowing plans, physicians, and pharmacists to efficiently communicate about the prescription drugs a beneficiary is taking.<sup>38</sup> To encourage its adoption, CMS established standards for e-prescribing under Part D, including standards related to formulary and benefits, medication history, fill status notification, and identification of individual health care providers.<sup>39</sup>

Finally, through its Sentinel Initiative, FDA will create a system to monitor the performance of prescription drugs, as well as medical devices, for potential problems such as ADEs. This initiative will link Medicare Part D prescription drug data, which became available to

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<sup>36</sup> CMS, "Medicare Prescription Drug Manual," ch. 7, § 30.1. Available online at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManualChap7Quality.pdf>. Accessed on April 11, 2008.

<sup>37</sup> CMS, "Medicare Prescription Drug Manual," ch. 7, § 30.2. Available online at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManualChap7Quality.pdf>. Accessed on April 11, 2008.

<sup>38</sup> CMS, "E-Prescribing Tools To Help Prevent Adverse Drug Interactions Press Release," April 2, 2008. Available online at <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3025&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date>. Accessed on June 18, 2008.

<sup>39</sup> 73 Fed. Reg. 18918 (Apr. 7, 2008).

Federal agencies in May 2008, with Medicare inpatient and outpatient data in an attempt to identify ADEs that occurred.<sup>40</sup> Although MA-PD inpatient and outpatient data are not collected by CMS and are not included in the initiative, FDA will have access to the Medicare Part D prescription drug data for more than 25 million beneficiaries.

#### **Office of Inspector General and Related Work**

The Kaiser Family Foundation issued a study in January 2008 that concluded that SNPs' value was uncertain, stating that further information was essential for assessing them.<sup>41</sup> In addition, Congress mandated a report from CMS concerning SNPs, to be completed no later than December 31, 2007.<sup>42</sup> Congress required that the report assess the cost and quality of services SNPs provide to beneficiaries. As of September 2008, the report has yet to be released.

The Institute of Medicine issued a congressionally mandated report in July 2006 on the nature and causes of medication errors and ADEs, their impact on patients, and other issues concerning them in the national population.<sup>43</sup> The study found that the rates of medication errors and preventable ADEs are high, but that effective strategies to prevent medication errors and ADEs, such as e-prescribing, physician and patient education, and pharmacist involvement, are available.

The Tax Relief and Health Care Act of 2006 requires the Inspector General to report to Congress regarding the incidence of "never events" (preventable serious adverse events) for Medicare beneficiaries, including types of events and payments by any party.<sup>44</sup> This report is one in a series that the Office of Inspector General is conducting concerning adverse events for Medicare beneficiaries, including those that occur in hospitals. This report explores potentially inappropriate drug pairs that may lead to ADEs.

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<sup>40</sup> CMS, "New Efforts to Help Improve Medical Products for Patient Safety and Quality of Medical Care," May 22, 2008. Available online at <http://www.hhs.gov/news/press/2008pres/05/20080522a.html>. Accessed on August 27, 2008.

<sup>41</sup> J.D. Verdier, et al., "Do We Know If Medicare Advantage Special Needs Plans Are Special?" Medicare Issue Brief, The Henry J. Kaiser Foundation, January 2008. Available online at <http://www.kff.org/medicare/upload/7729.pdf>. Accessed on April 14, 2008.

<sup>42</sup> MMA, P.L. No. 108-173 § 231, Social Security Act § 1851 note, 42 U.S.C. § 1395w-21 note.

<sup>43</sup> Philip Aspden, et al., Institute of Medicine of the National Academies, "Preventing Medication Errors: Quality Chasm Series," 2007.

<sup>44</sup> The Tax Relief and Health Care Act of 2006, P.L. No. 109-432 § 203.

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## METHODOLOGY

This study compares SNP beneficiaries' drug utilization, cost, and exposure to potentially inappropriate drug pairs to those of other MA-PD beneficiaries. These comparisons provide insights into the population of beneficiaries enrolled in SNPs and other MA-PDs using measures related to prescription drug use.

### Scope

This study does not analyze SNP or other MA-PD efforts to manage prescription drug use or to reduce beneficiaries' exposure to potentially inappropriate drug pairs. Instead, our analysis focuses on comparing SNP beneficiaries to other MA-PD beneficiaries. Prescription drug data are the only encounter-level data available for Medicare managed care plans. These data allow for a comparison of SNP beneficiaries to other MA-PD beneficiaries, but do not allow for a comparison of plans' programs for managing prescription drug use.

We limited our analysis to therapeutic duplications and drug-drug interactions. We focused on these because they are evident through prescription drug data and because they are defined in accepted industry resources.

### Data Sources

We used three data sources to conduct this study: (1) 2006 Part D Prescription Drug Event (PDE) data, (2) August 2007 First DataBank drug product information data, and (3) 2006 CMS plan-level descriptive data.

CMS requires plans providing prescription drug coverage to submit PDE data for payment purposes. Each drug event included in these data represents the dispensing of a drug or a medical supply for the injection of insulin.

For more information on our data sources and other aspects of our methodology, see Appendix A.

### Data Analysis

We analyzed all prescriptions for 634,000 SNP beneficiaries and 5.8 million other MA-PD beneficiaries in 2006. We used First DataBank to obtain product information for each prescription and

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CMS's plan-level descriptive data to determine whether plans were SNPs or other MA-PDs.

*Calculating prescription drug utilization.* To assess beneficiary drug utilization within SNPs versus that in other MA-PDs in 2006, we calculated the average number of prescriptions filled per beneficiary. We used PDE data, normalized by the number of days that the prescriptions covered, to calculate the number of prescriptions filled by beneficiaries. We considered PDE data with days of supply less than or equal to 44 days as one prescription. PDE data with days of supply greater than 44 but less than or equal to 74 were counted as two prescriptions. PDE data with days of supply greater than 74 were counted as three prescriptions.

We also determined which drugs were most frequently dispensed to SNP and other MA-PD beneficiaries during 2006. We based our count of drugs on the Ingredient List Identifier for each drug. The Ingredient List Identifier represents a unique combination of active ingredients, regardless of manufacturer, package size, dosage form, route of administration, or strength. This identifier does not distinguish whether a drug is the generic or brand name version.

*Calculating prescription drug costs.* We calculated the prescription drug costs incurred by SNPs and other MA-PDs on behalf of their beneficiaries at the point of sale. We did not calculate net costs because they are not captured in the PDE data. To calculate the cost of prescription drugs, we used the ingredient cost field provided in the PDE data, which represents the cost of the drug. It does not include any additional administrative costs, such as the dispensing fee paid to pharmacies.

Using these data, we calculated the average annual prescription drug cost per beneficiary for SNPs and other MA-PDs. We also calculated the average cost per prescription for both SNP and other MA-PD beneficiaries, the overall average cost per prescription for the most frequently dispensed drugs for SNP and other MA-PD beneficiaries, and the average cost paid by SNPs and other MA-PDs for the most frequently dispensed drugs for SNP beneficiaries.

*Calculating potential therapeutic duplications and drug-drug interactions.* For our analysis of potential therapeutic duplications and drug-drug interactions, we did not include beneficiaries who filled prescriptions under more than one plan. We did this to avoid counting potential

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therapeutic duplications and drug-drug interactions involving drugs from two different plans. Excluding these 400,000 beneficiaries left 534,000 SNP beneficiaries and 5.5 million other MA-PD beneficiaries in our analysis of potential therapeutic duplications and drug-drug interactions.

To determine when potential therapeutic duplications occurred, we used First DataBank's Duplicate Therapy Module. This module provides information on whether duplication within a therapeutic class increases the risk of toxicity.

To determine when potential drug-drug interactions occurred, we used First DataBank's Drug-Drug Interaction Module. First DataBank uses a system of flags to identify when two drugs potentially interact if taken simultaneously and assigns each interaction a severity level. See Table 1 for more detail on First DataBank's severe, serious, and moderate severity levels.

<b>Table 1: Severity Levels of Drug-Drug Interactions</b>	
<b>Severity Level</b>	<b>Description of Interaction</b>
Severe	These medicines are not usually taken together. Contact health care professional (e.g., doctor or pharmacist) for more information.
Serious	These medicines may interact and cause very harmful effects. Contact health care professional for more information.
Moderate	These medicines may cause some risk when taken together. Contact health care professional for more information.

Source: First DataBank Drug-Drug Interaction Module, 2007.

## **Data Limitations**

This study only identifies potential therapeutic duplications and drug-drug interactions. It does not determine whether these potentially inappropriate drug pairs were prescribed or dispensed purposefully or in error. In addition, this study does not determine that beneficiaries took the drugs they were dispensed nor whether beneficiaries who took the drugs experienced any ill effects. Thus, this study does not determine that an ADE occurred. Rather, the potential therapeutic duplications and drug-drug interactions identified in this report are instances in which drug pairs created the circumstances in which an ADE could occur and thus may have required monitoring by a health care professional.



## I N T R O D U C T I O N

This study uses only one source of information, First DataBank, to identify potential therapeutic duplications and drug-drug interactions. First DataBank is widely used by pharmacists and researchers as a tool for obtaining drug information, including alerts for therapeutic duplications and drug-drug interactions. However, individual plans may use other databases and tools that may identify potential therapeutic duplications or drug-drug interactions differently from First DataBank.

We did not independently verify the First Databank modules' accuracy in identifying potential therapeutic duplications and drug-drug interactions in the Medicare population. Further, we did not compare First DataBank to other sources for identifying potential therapeutic duplications and drug-drug interactions.

### **Standards**

This study 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.

## ► FINDINGS

### **On average, SNP beneficiaries had higher prescription drug utilization and costs than other MA-PD beneficiaries**

On average, SNP beneficiaries filled 11 percent more prescriptions and had 49 percent higher average prescription drug costs than other MA-PD beneficiaries in 2006. SNP beneficiaries' higher prescription drug utilization and costs indicate that they may be different from other MA-PD beneficiaries, at least as far as their drug utilization and costs are concerned.

### **On average, SNP beneficiaries filled 11 percent more prescriptions than other MA-PD beneficiaries**

On average, SNP beneficiaries filled 40 prescriptions during 2006. Other MA-PD beneficiaries filled 36 prescriptions on average during 2006. In addition, 25 percent of SNP beneficiaries filled 56 prescriptions or more, compared to 21 percent of other MA-PD beneficiaries.

SNP beneficiaries filled, on average, five prescriptions per month during 2006. Other MA-PD beneficiaries filled, on average, between four and five prescriptions per month.

Overall, 93 percent of prescriptions were refills during 2006. For SNP beneficiaries, 90 percent of prescriptions were refills; for other MA-PD beneficiaries, 93 percent were refills. Frequent refills indicate the use of maintenance drugs for chronic conditions rather than drugs to treat acute episodes.

### **On average, the annual prescription drug cost per SNP beneficiary was 49 percent higher than that of other MA-PD beneficiaries**

The average annual prescription drug cost per SNP beneficiary was \$2,104 in 2006, with most beneficiaries' prescription drug costs ranging between \$390 and \$2,600. In comparison, other MA-PD beneficiaries had an average annual prescription drug cost of \$1,411 per beneficiary. In fact, 79 percent of other MA-PD beneficiaries had annual prescription drug costs that were below the SNP beneficiaries' average annual prescription drug cost of \$2,104.

The fact that SNP beneficiaries' average annual prescription drug cost was higher than other MA-PD beneficiaries' may be partially explained by drug utilization. As previously indicated, SNP beneficiaries filled, on average, four more prescriptions than other MA-PD beneficiaries.

In addition, the average cost per prescription for SNP beneficiaries was greater than that for other MA-PD beneficiaries. On average, SNP

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beneficiaries' prescriptions cost \$53 compared to \$39 for other MA-PD beneficiaries. The fact that SNP beneficiaries' average cost per prescription was higher than that of other MA-PD beneficiaries may be explained by SNP beneficiaries' utilization of costlier drugs, their low utilization of less-expensive 90-day prescriptions, and the prices negotiated between plans and pharmacies.

SNP beneficiaries used drugs that were somewhat different from, and more costly than, those used by other MA-PD beneficiaries. For example, there were nine drugs that differed when comparing the 40 drugs most frequently dispensed to SNP beneficiaries and other MA-PD beneficiaries. Using the overall average prescription drug cost as a measure of market value, the nine drugs found only on the SNP list of top drugs were more expensive drugs. The overall average cost per prescription for these nine drugs was \$86, compared to \$22 for the nine drugs found only on the list of top drugs used by other MA-PD beneficiaries.

In addition, SNP beneficiaries had a lower utilization of 90-day prescriptions. Only 1 percent of SNP beneficiaries' prescriptions were for 90 days compared to 14 percent for other MA-PD beneficiaries. These extended prescriptions cost 57 percent less per day than 30-day prescriptions. SNP beneficiaries' low utilization of 90-day prescriptions may be an intentional strategy by SNPs to more closely monitor their special needs population.

Finally, in some cases, SNPs paid pharmacies more for the same drug than other MA-PDs. For example, SNPs paid more per prescription than other MA-PDs for 34 of the 40 drugs most frequently dispensed to SNP beneficiaries. SNPs paid as much as 52 percent more than other MA-PDs for these drugs. See Appendix B for a breakout of this analysis by prescription drug.

SNPs may have paid more for some drugs than other MA-PDs because of differences in negotiating power, either because SNPs are not part of larger organizations or because they have lower enrollment. Lack of affiliation with larger organizations and lower enrollment translates into less market share to use as a tool to bargain for lower drug prices. Overall, SNPs typically have lower enrollment than other MA-PDs. In fact, for 2008, 63 percent of SNPs have fewer than 500 beneficiaries enrolled in their plans.

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### **Despite SNP beneficiaries' higher rates of drug utilization, SNP and other MA-PD beneficiaries were similarly exposed to potentially inappropriate drug pairs**

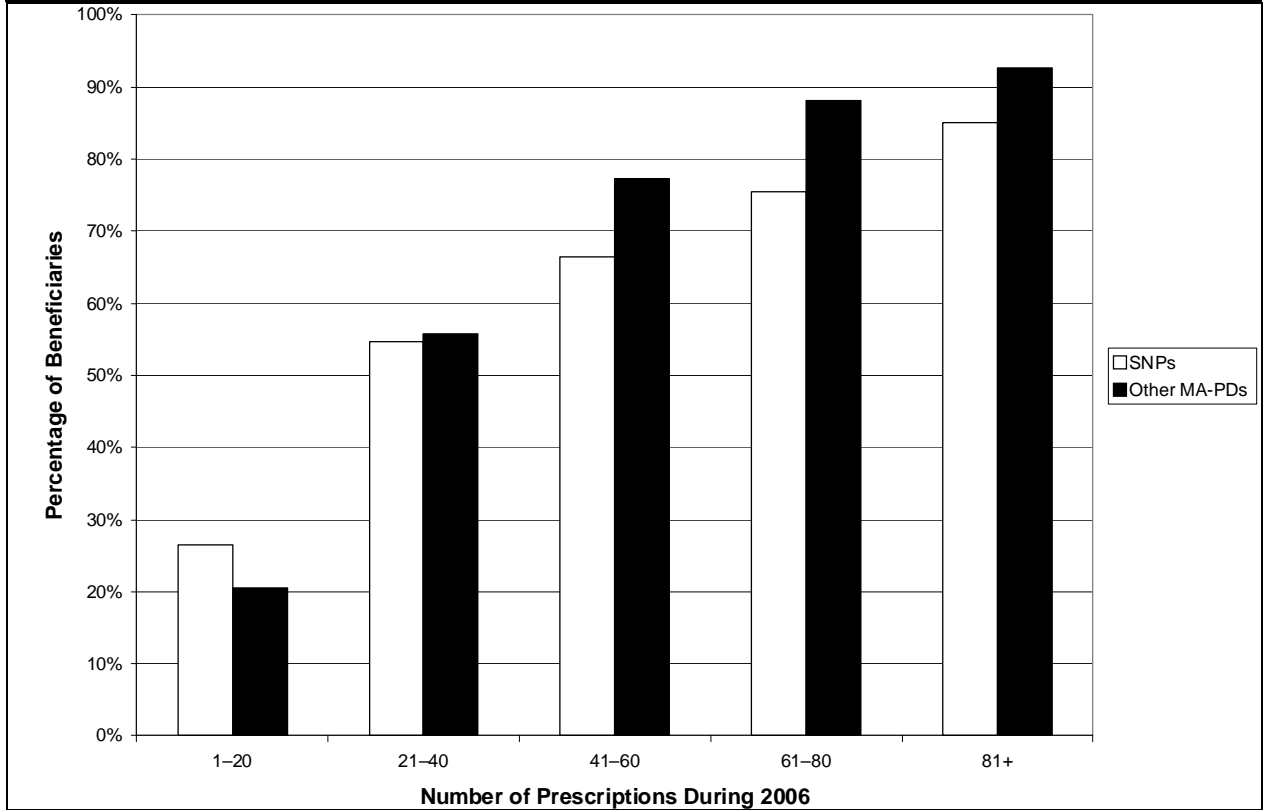
Because SNP beneficiaries filled more prescriptions for more drugs than other MA-PD beneficiaries, they might be expected to be at greater risk of exposure to potentially inappropriate drug pairs. The greater the drug utilization and the more different drugs a beneficiary takes, the greater the opportunity for exposure to potentially inappropriate drug pairs. SNP beneficiaries filled 11 percent more prescriptions than other MA-PD beneficiaries, on average. In addition, on average, SNP beneficiaries filled prescriptions for 10 different drugs while other MA-PD beneficiaries filled prescriptions for 8 different drugs. Despite this higher drug utilization, the same percentage of SNP beneficiaries were exposed to at least one potentially inappropriate drug pair as other MA-PD beneficiaries. Fifty-three percent of both SNP and other MA-PD beneficiaries were exposed to at least one potential therapeutic duplication or drug-drug interaction, which may or may not have led to an ADE.

### **At higher levels of prescription drug utilization, SNP beneficiaries were less likely to be exposed to a potentially inappropriate drug pair than other MA-PD beneficiaries**

In general, exposure to potentially inappropriate drug pairs is positively correlated to the number of prescriptions filled by beneficiaries. As utilization increased, a greater percentage of SNP and other MA-PD beneficiaries were exposed to at least one potentially inappropriate drug pair. However, at higher levels of prescription drug utilization, SNP beneficiaries were less likely than other MA-PD beneficiaries to be exposed to a potentially inappropriate drug pair. For example, 67 percent of SNP beneficiaries who filled between 41 and 60 prescriptions were exposed to a potential therapeutic duplication or drug-drug interaction, compared to 77 percent of other MA-PD beneficiaries. The chart on the following page illustrates that SNP beneficiaries were less likely to be exposed to a potential therapeutic duplication or drug-drug interaction than other MA-PD beneficiaries at higher levels of prescription drug utilization.

FINDINGS

Chart 1: Percentage of SNP and Other MA-PD Beneficiaries Exposed to a Therapeutic Duplication or Drug-Drug Interaction for Ranges of Prescriptions



Source: Office of Inspector General (OIG) analysis of 2006 PDE data, 2008.

**The majority of potentially inappropriate drug pairs were drug-drug interactions of moderate risk for both SNP and other MA-PD beneficiaries**

The type and severity of the potentially inappropriate drug pairs SNP and other MA-PD beneficiaries were exposed to were similar during 2006. Over half of

potentially inappropriate drug pairs for both SNP and other MA-PD beneficiaries were drug-drug interactions, most of which were of moderate risk.

**For both SNP and other MA-PD beneficiaries, the majority of potentially inappropriate drug pairs were drug-drug interactions**

Drug-drug interactions accounted for 65 percent of potentially inappropriate drug pairs for both SNP and other MA-PD beneficiaries. The remaining 35 percent of potentially inappropriate drug pairs were

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therapeutic duplications. On average, SNP and other MA-PD beneficiaries who were exposed to potentially inappropriate drug pairs experienced eight potentially inappropriate drug pairs, of which six were drug-drug interactions.

### **For both SNP and other MA-PD beneficiaries, the majority of potential drug-drug interactions were of moderate risk**

Overall, 83 percent of potential drug-drug interactions were of moderate risk. In other words, five of the six potential drug-drug interactions, on average, were of moderate risk for beneficiaries who experienced potential drug-drug interactions. Eighty-four percent of potential drug-drug interactions for SNP beneficiaries and 83 percent for other MA-PD beneficiaries were of moderate risk.

Moderate drug-drug interactions may cause some risk to the beneficiary. The moderate drug-drug interactions identified in this report could have led to problems such as low blood pressure, nausea, fatigue, or muscle weakness.

*Severe and serious interactions accounted for 17 percent of potential drug-drug interactions.* Severe interactions, which result from two drugs that are contraindicated and should not usually be taken together, accounted for 1 percent of potential drug-drug interactions for both SNP and other MA-PD beneficiaries. Serious interactions, which may cause very harmful effects, accounted for 16 percent of all potential drug-drug interactions. Serious drug-drug interactions accounted for 15 percent of potential drug-drug interactions for SNP beneficiaries and 16 percent for other MA-PD beneficiaries. On average, one of the six potential drug-drug interactions for beneficiaries exposed to potentially inappropriate drug pairs was of either severe or serious risk.

Severe and serious drug-drug interactions may require a change in drug regimen or monitoring by a health care professional. These interactions can lead to problems such as gastrointestinal damage, abnormal heart rates, or bleeding complications.

Certain drugs were more likely to be involved in severe or serious potential drug-drug interactions. These drugs treat a variety of ailments, such as heart conditions, high blood pressure, blood clots, overactive bladders, infections, pain, high cholesterol, gastrointestinal disorders, and low potassium. See Appendix C for a list of the 20 drugs most frequently involved in severe or serious potential drug-drug interactions.

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Two drugs, potassium chloride and warfarin sodium, stand out because of the frequency with which they were involved in either a severe or serious potential drug-drug interaction. Health care professionals are generally aware of both drugs' potential risks and may have provided increased observation of beneficiaries taking these drugs.

Potassium chloride was involved in 34 percent of severe potential drug-drug interactions. Potassium chloride can produce ulcerative lesions of the gastrointestinal tract.<sup>45</sup> Some of the severe potential drug-drug interactions in which it was involved could have also produced gastrointestinal damage. Two of the drugs most frequently involved in potential drug-drug interactions with potassium chloride were lisinopril and spironolactone. These drugs are often prescribed in combination with potassium chloride but may require a decrease in the dose of potassium chloride and monitoring by a health care professional.

Warfarin sodium was involved in 17 percent of serious potential drug-drug interactions. Warfarin sodium can increase the risk of hemorrhage.<sup>46</sup> Some of the serious potential drug-drug interactions in which it was involved could have produced bleeding complications. Two of the drugs most frequently involved in potential drug-drug interactions with warfarin sodium were lovastatin and levothyroxine sodium. These drugs are often prescribed in combination with warfarin sodium but may require a decrease in the dose of warfarin sodium and monitoring by a health care professional.

### **For both SNP and other MA-PD beneficiaries, the majority of potentially inappropriate drug pairs recurred**

Overall, 74 percent of all potentially inappropriate drug pairs recurred. Of these recurring potentially inappropriate drug pairs, 26 percent were produced by unique drug pairs; the rest were recurrences of these unique drug pairs. Seventy-seven percent of all potentially inappropriate drug pairs recurred for SNP beneficiaries and 74 percent recurred for other MA-PD beneficiaries.

Seventy-nine percent of all severe and 80 percent of all serious potential drug-drug interactions were recurring errors. Twenty-three percent of

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<sup>45</sup> "Potassium Chloride." Physicians' Desk Reference, 60<sup>th</sup> ed., 2006, pp. 3047–3048.

<sup>46</sup> "Coumadin (Warfarin Sodium)." Physicians' Desk Reference, 60<sup>th</sup> ed., 2006, pp. 932–937.

both the severe and serious potential drug-drug interactions that recurred were produced by unique drug pairs.

The fact that most potentially inappropriate drug pairs recurred suggests that either the risks of the potential therapeutic duplications and drug-drug interactions were known and outweighed by medical necessity or that the physician or pharmacy was unaware of the risks. In some cases, health professionals may have been monitoring beneficiaries for potentially dangerous effects. In other cases, beneficiaries may have been repeatedly exposed to potential therapeutic duplications and drug-drug interactions, some of a severe or serious nature, that should have been detected and corrected.

**For both SNP and other MA-PD beneficiaries, the majority of potentially inappropriate drug pairs involved drugs prescribed by the same physician and filled by the same pharmacy**

Overall, 66 percent of all potentially inappropriate drug pairs involved drugs prescribed by the same physician and dispensed by the same pharmacy. Twenty-two percent of all potentially inappropriate drug pairs were filled at the same pharmacy on the same day.

Seventy-three percent of all potentially inappropriate drug pairs involved drugs that were prescribed by the same physician. In some of these cases, the physician may have been unaware of the potential risks of prescribing the two drugs together. One study of physicians' knowledge of drug-drug interactions showed that they could correctly classify drugs as adversely interacting only about half of the time.<sup>47</sup>

Moreover, 88 percent of all potentially inappropriate drug pairs involved drugs that were filled by the same pharmacy. Pharmacies typically have concurrent drug utilization review systems that alert pharmacists to potentially inappropriate drug pairs. However, one study found that pharmacists override the majority of alerts, concluding that the high volume of alerts may be overwhelming.<sup>48</sup> Another study found that

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<sup>47</sup> Peter A. Glassman, et al., 2002. "Improving recognition of drug interactions: benefits and barriers to using automated drug alerts." *Medical Care*, vol. 40, pp. 1161–1171.

<sup>48</sup> Michelle A. Chui and Michael T. Rupp, 2006. "Evaluation of online prospective DUR programs in community pharmacy practice." *Journal of Managed Care Pharmacy*, vol. 6, pp. 27–32.



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pharmacists also may not always be aware of the potential risks of two drugs when taken together.<sup>49</sup>

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<sup>49</sup> Rich A. Weideman, et al., 1999. "Pharmacist recognition of potential drug interactions." *American Journal of Health System Pharmacy*, vol. 56, pp. 1524–1529.

## ► R E C O M M E N D A T I O N

SNP beneficiaries filled more prescriptions and had higher average prescription drug costs than other MA-PD beneficiaries. This indicates that SNP beneficiaries may be different from other MA-PD beneficiaries, at least as far as their drug utilization and costs are concerned. In addition, although SNP beneficiaries had higher drug utilization than other MA-PD beneficiaries on average, SNP and other MA-PD beneficiaries were similarly exposed to potentially inappropriate drug pairs. At higher levels of drug utilization, SNP beneficiaries were less likely to be exposed to a potentially inappropriate drug pair than other MA-PD beneficiaries.

Regardless of whether beneficiaries were enrolled in a SNP or other MA-PD, the type and severity of their potentially inappropriate drug pairs were similar. Although most of the potential drug-drug interactions were of moderate risk, 17 percent posed severe or serious risk. Thus, in some cases beneficiaries may have been needlessly exposed to serious risk, with some potentially leading to an ADE. Therefore we make the following recommendation:

### **CMS Should Help SNPs and Other MA-PDs Provide Physicians and Pharmacists the Information They Need To Prevent Inappropriate Drug Pairs Leading to ADEs**

For SNP and other MA-PD beneficiaries, 66 percent of potentially inappropriate drug pairs involved drugs that were prescribed by the same physician and filled by the same pharmacy. Although some of the potentially inappropriate drug pairs could have been intentionally prescribed because medical professionals judged that the benefits outweighed the risks, others could have been errors. Thus, if physicians and pharmacists had been given the right information, some of these potentially inappropriate drug pairs could have been avoided.

CMS should encourage plans to fully implement e-prescribing programs as one approach with the potential to help physicians and pharmacists screen for and prevent ADEs. E-prescribing can improve communication about beneficiaries' medication histories, thus providing the information necessary to prevent ADEs. Standards for e-prescribing under Part D include a standard for allowing physicians, pharmacists, and Part D plans (which include SNPs and other MA-PDs) to communicate about beneficiaries' medication histories, including information that may help identify ADEs.

In addition, CMS should ask FDA, as part of its Sentinel Initiative, to develop a list of drug combinations that are likely to be involved in

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severe or serious ADEs for the Medicare population. Once FDA has compiled this list, CMS should distribute this targeted list of drug combinations to SNPs and other MA-PDs to help screen for potentially inappropriate drug pairs. As previously mentioned, one study found that concurrent drug utilization reviews may be flagging so many interactions that pharmacists find them more troublesome than helpful. A targeted list of potentially inappropriate drug pairs most likely to be involved in severe or serious ADEs could help SNPs and other MA-PDs target specific drugs and drug combinations to prevent ADEs.

This list could also help SNPs and other MA-PDs better monitor beneficiaries at risk for an ADE. To this end, CMS could encourage plans to expand eligibility for MTM services to beneficiaries filling prescriptions for drugs on the list of drug combinations likely to be involved in severe or serious ADEs.

Obtaining the information needed to prevent ADEs is a necessary first step, but it may not be sufficient. As mentioned earlier, providers can be overwhelmed by the amount of information they receive, rendering the information useless. To overcome this, CMS should encourage plans to provide tools to assist physicians and pharmacists in appropriately analyzing and using the information they receive. CMS could help plans provide educational material and/or training to physicians for identifying ADEs.

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

CMS concurred with our recommendation to help SNPs and other MA-PDs provide physicians and pharmacists the information they need to prevent inappropriate drug pairs that could lead to ADEs. CMS noted that Part D sponsors are currently required to maintain systems to monitor drug utilization, including the use of potentially inappropriate drug pairs.

In addition, CMS stated that it supports a number of efforts aimed at preventing inappropriate drug pairs that could lead to ADEs. In particular, CMS cited efforts to establish e-prescribing programs in Part D that provide prescription information and medication history to physicians and pharmacies. CMS is also collaborating with FDA on the Sentinel Project, which is designed to augment postmarketing surveillance of approved medical products to improve information on

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potential risks and drug-drug interactions. Finally, CMS is evaluating MTM best practices to assist MTM programs in meeting their statutory goal of optimizing therapeutic outcomes through improved use of Part D medications and reducing risk of adverse events.

However, CMS expressed concern about our use of the First Databank drug product information database to identify potentially inappropriate drug pairs. CMS stated that First Databank algorithms have not been specifically validated for use in the Medicare population. Although this may be true, First DataBank is widely used by pharmacists, researchers, and health care plans, including the Department of Veterans Affairs, State Medicaid programs, and Part D sponsors, to identify inappropriate drug pairs.

CMS suggested that any assessment of inappropriate drug pairs rely on information from FDA because there is no commercially available software that has been validated for this use in the Medicare population. We did not rely on information from FDA because FDA does not maintain drug information on potential risks and interactions in a format that would allow for a systematic assessment. Further, FDA has noted that there are barriers to inclusion of the elderly in clinical trials, leading us to believe that currently no complete and validated source of information specifically related to the Medicare population exists.<sup>50</sup> Perhaps FDA's Sentinel Project will help fill this gap.

For the full text of CMS's comments, see Appendix D.

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<sup>50</sup> Michelle Meadows, "Medication Use and Older Adults." FDA Consumer Magazine, July-August 2006. Available online at [http://www.fda.gov/fdac/features/2006/406\\_olderadults.html](http://www.fda.gov/fdac/features/2006/406_olderadults.html). Accessed on November 14, 2008.

## Detailed Methodology

This study analyzes Prescription Drug Event (PDE) data for Special Needs Plans (SNP) and other Medicare Advantage Prescription Drug plans (MA-PD). We did not analyze stand-alone prescription drug plans.

### Data Sources

We used three data sources to conduct this study: (1) 2006 PDE data, (2) August 2007 First DataBank drug product information data, and (3) 2006 Centers for Medicare & Medicaid Services (CMS) plan-level descriptive data.

CMS requires plans providing Part D drug coverage to submit PDE data for payment purposes. Each drug event included in these data represents the dispensing of a drug or medical supply for the injection of insulin. These data contain the beneficiary's identification number, the Food and Drug Administration's National Drug Code (NDC),<sup>51</sup> the date of service, the number of days that the drug is supplied, the drug's costs, the prescribing physician, and the pharmacy where the prescription was filled. Our analysis included final action PDE claims submitted by SNPs and other MA-PDs for 2006.<sup>52</sup>

First DataBank is a database containing drug product information, such as drug name and therapeutic class, for each NDC. The August 2007 First DataBank data contained information on all drugs covered by Part D in 2006, but with more up-to-date drug information than prior versions of the First DataBank data.

First DataBank also includes a Duplicate Therapy Module and a Drug-Drug Interaction Module. The Duplicate Therapy Module provides information on whether two drugs from the same therapeutic class, when taken simultaneously, increase the risk of toxicity. The Drug-Drug Interaction Module identifies drug-drug interactions and their severity level.

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<sup>51</sup> An NDC is a three-part universal identifier that specifies the drug manufacturer's name, the drug form and strength, and the package size.

<sup>52</sup> Final action claims are those CMS uses to reconcile payments to plans. A PDE record is submitted each time a beneficiary fills a prescription covered under Part D. The PDE records may be amended or deleted up to 6 months after the end of the payment year. After that point, CMS considers them to be final action claims.

CMS publishes comprehensive plan-level data on all Part D plans that include contract and plan benefit package numbers, organization names, enrollment, and whether a plan is a SNP.

### **Data Analysis**

The 2006 PDE data for SNPs and other MA-PDs include 6.4 million beneficiaries with 187 million prescriptions from 1,879 plans. We removed 137,000 prescriptions that were listed as partial fills because they create the possibility of misstating drug utilization, costs, and therapeutic duplications and drug-drug interactions. This removed from our analysis 1,134 beneficiaries who only partially filled prescriptions.

*Calculating prescription drug utilization and costs.* We analyzed cost and utilization separately for each beneficiary and for each plan through which he or she filled a prescription. We then aggregated this information to represent the totals for SNP beneficiaries and other MA-PD beneficiaries.

We counted prescriptions and costs according to the plan that paid for each prescription. To reflect utilization and costs, we used a weighted enrollment to compensate for beneficiaries who were enrolled in multiple plans during 2006. About 400,000 of the 6.4 million beneficiaries filled prescriptions from more than one plan. Of these, 100,000 filled prescriptions from both a SNP and another MA-PD.

We calculated weighted enrollment using prescription fill dates as a proxy for days of enrollment in plans. Beneficiaries with two plans were considered to be enrolled in Plan A from January 1 until midway between their last prescription in Plan A and their first prescription in Plan B. We calculated enrollment in Plan B from that midpoint until December 31. Enrollment for beneficiaries with more than two plans was calculated similarly using the first and last prescription fill dates for each plan.

To be conservative, we assumed a full year of enrollment when weighting beneficiaries for our analysis. Assuming a full year of enrollment for all beneficiaries resulted in a larger enrollment figure than assuming partial-year enrollment, which led to lower, more conservative estimates of average utilization and cost.

If a beneficiary was enrolled in multiple SNPs, enrollment weights for these plans were added together to form the beneficiary's SNP enrollment weight. Enrollment weights for other MA-PDs were

similarly added together to form the beneficiary's other MA-PD enrollment weights. The weights for each beneficiary equal one when summed.

The weighting of beneficiaries resulted in a weighted enrollment of 634,000 for SNPs and 5.8 million for other MA-PDs. We used these weighted enrollment figures to calculate average drug utilization and cost.

*Assessing the difference in SNP beneficiaries' average annual prescription drug cost compared to that of other MA-PD beneficiaries.* To determine potential explanations for differences between the average annual prescription drug cost per SNP beneficiary and that of other MA-PD beneficiaries, we analyzed prescription drug utilization and cost factors that might affect overall cost.

To analyze prescription drug utilization, we compared the number of prescriptions filled by SNP beneficiaries to the prescriptions filled by other MA-PD beneficiaries.

To analyze differences in cost, we compared the drug mix for SNP and other MA-PD beneficiaries to explore whether the difference in overall cost was related to SNP beneficiaries requiring more costly types of drugs. To do this, we compared the 40 drugs most dispensed to SNP beneficiaries to the 40 drugs most dispensed to other MA-PD beneficiaries. These drugs accounted for 46 percent of SNP beneficiaries' drug utilization and 56 percent of other MA-PD beneficiaries' drug utilization.

To determine the cost of the drugs that differed between the two lists of most frequently dispensed drugs, we calculated an overall average prescription cost per drug. This was used as a proxy for the market-value of the drug. The overall average prescription drug cost was calculated by totaling the amount paid by both SNPs and other MA-PDs for each drug and dividing this by total utilization.

We also determined whether SNP and other MA-PD beneficiaries utilized 30- and 90-day prescriptions differently, given that 90-day prescriptions are typically less expensive. We defined a 30-day prescription as any prescription with days of supply less than or equal to 44 days. We defined a 90-day prescription as any prescription with days of supply greater than 74 days.

Finally, to assess drug prices paid by SNPs and other MA-PDs for the same drug, we compared the average prescription costs paid by plans for each drug. We did this for the 40 drugs most dispensed to SNP beneficiaries. We compared the prices SNPs paid for these top 40 drugs to the prices MA-PDs paid for the same drugs. We repeated these calculations for 30-day prescriptions and 90-day prescriptions, normalized to 30-day prescription costs.

*Calculating potential therapeutic duplications and drug-drug interactions.*

For our analysis of potential therapeutic duplications and drug-drug interactions, we did not include beneficiaries who filled prescriptions under more than one plan. We did this to avoid counting potential therapeutic duplications and drug-drug interactions involving drugs from two different plans.

Beneficiaries who switch plans might also switch their physician or pharmacy to accommodate their new plan's network. A new plan, pharmacy benefit management organization, pharmacy, or physician might not have medication histories for these beneficiaries. A greater number of potential therapeutic duplications and drug-drug interactions may result if a new physician is not aware of drugs a beneficiary is taking. Thus, the prevalence of potential therapeutic duplications and drug-drug interactions in this population is not comparable to the vast majority of beneficiaries who were enrolled in a single plan.

Excluding these beneficiaries left 534,000 SNP beneficiaries and 5.5 million other MA-PD beneficiaries in our analysis of potential therapeutic duplications and drug-drug interactions. We did not weight enrollment for our analysis of potential therapeutic duplications and drug-drug interactions because the beneficiaries in this analysis were enrolled only in one plan.

We counted a potential therapeutic duplication when the following three criteria were met for a beneficiary: (1) two drugs were from the same therapeutic class, (2) the therapeutic class did not allow duplications according to First DataBank, and (3) the two drugs' supply periods overlapped for at least 25 percent of the shortest of the supply periods. Because plans often limit beneficiaries' ability to refill a prescription until the last 25 percent of the supply period, we used this criterion to reduce the possibility of including early refills in our count of potential therapeutic duplications.



We counted a potential drug-drug interaction when the following two criteria were met for a beneficiary: (1) two drugs were flagged by First DataBank as interacting when taken simultaneously, and (2) the two drugs had supply periods that overlapped for at least 2 days. We used 2 days as the overlap period to avoid cases in which one prescription ended and the other began on the same day. We did not use the overlap period used for therapeutic duplications because there is not the same risk of inappropriately counting an early refill as a potential drug-drug interaction.

To identify prescriptions that appeared to represent a drug change in response to the detection of a drug-drug interaction, we looked for potential therapeutic duplications that: (1) occurred within the fill period of a potential drug-drug interaction, (2) involved one drug in common with the potential drug-drug interaction, and (3) only occurred once. Further, we only considered cases in which the potential drug-drug interaction did not occur again after the therapeutic duplication. Over 190,000 therapeutic duplications appear to have been changes in medications to avoid potential drug-drug interactions. They represent 1 percent of all potential therapeutic duplications. Thus, the data contain some potential therapeutic duplications that may have been the result of a change in medication because of the detection of a drug-drug interaction.

*Assessing potential therapeutic duplications and drug-drug interactions.*

We analyzed exposure to potential therapeutic duplications and drug-drug interactions for each beneficiary. We then aggregated this information to represent totals for SNP beneficiaries and other MA-PD beneficiaries.

We calculated the percentage of beneficiaries who had at least one potential therapeutic duplication or drug-drug interaction for different ranges in the number of prescriptions. We divided beneficiaries into these ranges based on their number of prescriptions. For each range of prescription drug utilization, we counted the number of beneficiaries with at least one potential therapeutic duplication or drug-drug interaction and divided it by the total number of beneficiaries in that range.

To determine the average number of potential therapeutic duplications and drug-drug interactions among beneficiaries who were exposed to a potential therapeutic duplication or drug-drug interaction, we summed the number of potential therapeutic duplications and drug-drug

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interactions for all beneficiaries and divided this by the number of beneficiaries exposed to a potential therapeutic duplication or drug-drug interaction. For potential drug-drug interactions, we repeated this calculation for each severity level defined by First DataBank.

To find the top 20 drugs involved in severe and serious potential drug-drug interactions, we counted each occurrence of a unique drug in a severe and serious potential drug-drug interaction and found the drugs that were most frequently involved.

To calculate the percentage of recurring potential therapeutic duplications and drug-drug interactions, we found the instances in which a beneficiary was exposed to potential therapeutic duplications and drug-drug interactions involving the same pair of drugs more than once during 2006. We divided the number of recurring drug pairs by the total number of potential therapeutic duplications and drug-drug interactions to find the percentage that recurred. Thus, if potential therapeutic duplications and drug-drug interactions from a particular drug combination occurred every month of the year, we counted that as 12 recurring potential therapeutic duplications and drug-drug interactions.

To calculate the percentage of unique drug pairs involved in recurring potential therapeutic duplications and drug-drug interactions, we first totaled the number of unique drug pairs involved in potential therapeutic duplications and drug-drug interactions. We then divided this by the total number of recurring potential therapeutic duplications and drug-drug interactions. We repeated this calculation for severe and serious potential drug-drug interactions.

To determine how often two drugs involved in potential therapeutic duplications and drug-drug interactions were prescribed by the same physician or filled by the same pharmacy, we used the prescriber and provider identification numbers, respectively, provided in the PDE data. We then used the date of service to determine whether potential therapeutic duplications and drug-drug interactions were filled by the same pharmacy on the same day.



A P P E N D I X ~ B

**Differences in Cost for the Most Frequently Dispensed Prescription Drugs in Special Needs Plans**

**Table 2: Average Cost per 30-day, 90-day, and All Prescriptions for the 40 Drugs Most Frequently Dispensed to Special Needs Plan and Other Medicare Advantage Prescription Drug Plan\* Beneficiaries**

Drug Name	Average Cost per 30-Day Prescription		Average Cost per 90-Day Prescription Normalized to 30-Day Drug Supply		Average Cost per Prescription Normalized to 30-Day Drug Supply	
	SNPs	Other MA-PDs	SNPs	Other MA-PDs	SNPs	Other MA-PDs
Levothyroxine Sodium	\$8.31	\$8.19	\$6.60	\$6.92	\$8.22	\$7.59
Furosemide	\$2.46	\$2.19	\$2.23	\$2.14	\$2.45	\$2.15
Atorvastatin Calcium	\$89.40	\$86.50	\$85.52	\$81.40	\$89.18	\$84.12
Lisinopril	\$10.10	\$9.59	\$11.59	\$8.49	\$10.16	\$9.00
Metformin Hcl	\$16.42	\$15.26	\$19.40	\$17.74	\$16.50	\$16.14
Atenolol	\$3.71	\$3.21	\$4.41	\$2.91	\$3.73	\$3.03
Hydrochlorothiazide	\$2.58	\$2.58	\$2.26	\$1.82	\$2.56	\$2.14
Hydrocodone Bit/Acetaminophen	\$9.96	\$10.13	\$14.57	\$13.55	\$9.98	\$10.25
Amlodipine Besylate	\$54.34	\$53.24	\$51.97	\$50.53	\$54.22	\$52.41
Metoprolol Tartrate	\$3.93	\$3.44	\$4.17	\$4.69	\$3.93	\$3.89
Ranitidine Hcl	\$9.95	\$8.61	\$13.33	\$9.74	\$10.01	\$8.89
Potassium Chloride	\$11.49	\$9.45	\$8.69	\$8.13	\$11.36	\$8.94
Clopidogrel Bisulfate	\$118.21	\$115.33	\$105.78	\$108.20	\$117.66	\$113.04
Glipizide	\$11.72	\$11.12	\$11.08	\$9.05	\$11.68	\$10.29
Warfarin Sodium	\$11.88	\$14.61	\$12.65	\$12.82	\$11.90	\$14.02
Enalapril Maleate	\$10.20	\$8.94	\$11.56	\$11.40	\$10.23	\$9.61
Gabapentin	\$53.03	\$45.94	\$54.34	\$54.57	\$52.99	\$48.10
Lovastatin	\$34.18	\$27.48	\$30.91	\$22.00	\$33.83	\$24.12
Simvastatin	\$106.64	\$106.49	\$97.47	\$85.05	\$105.85	\$95.87
Alendronate Sodium	\$71.85	\$70.35	\$67.57	\$60.67	\$71.63	\$65.30

Source: Office of Inspector General analysis of 2006 Prescription Drug Event data, 2008.

\*Special Needs Plan = SNP

Medicare Advantage Prescription Drug Plan = MA-PD

A P P E N D I X B

**Table 2: Average Cost per 30-day, 90-day, and All Prescriptions for the 40 Drugs Most Frequently Dispensed to Special Needs Plan and Other Medicare Advantage Prescription Drug Plan Beneficiaries, continued**

Drug Name	Average Cost per 30-Day Prescription		Average Cost per 90-Day Prescription Normalized to 30-Day Drug Supply		Average Cost per Prescription Normalized to 30-Day Drug Supply	
	SNPs	Other MA-PDs	SNPs	Other MA-PDs	SNPs	Other MA-PDs
Sertraline Hcl	\$79.70	\$74.54	\$69.40	\$69.12	\$79.41	\$72.87
Diltiazem Hcl	\$34.54	\$34.75	\$34.75	\$31.52	\$34.53	\$33.46
Digoxin	\$4.30	\$4.33	\$3.73	\$4.03	\$4.28	\$4.19
Quetiapine Fumarate	\$201.75	\$149.47	\$194.69	\$146.53	\$201.63	\$148.47
Albuterol	\$12.86	\$11.33	\$15.72	\$12.96	\$12.87	\$11.34
Pantoprazole Sodium	\$110.13	\$109.18	\$104.67	\$104.33	\$109.97	\$107.89
Isosorbide Mononitrate	\$10.46	\$9.95	\$12.68	\$12.35	\$10.53	\$10.63
Trazodone Hcl	\$5.13	\$4.61	\$7.93	\$5.23	\$5.18	\$4.75
Omeprazole	\$53.50	\$39.65	\$44.49	\$31.06	\$53.14	\$34.88
Risperidone	\$210.95	\$166.17	\$227.87	\$180.75	\$211.03	\$167.49
Metoprolol Succinate	\$32.18	\$31.51	\$30.14	\$29.39	\$31.99	\$30.70
Rosiglitazone Maleate	\$125.14	\$123.57	\$120.70	\$118.62	\$124.90	\$122.04
Oxycodone Hcl/Acetaminophen	\$19.15	\$27.26	\$28.57	\$33.45	\$19.16	\$27.38
Fluoxetine Hcl	\$16.92	\$13.95	\$20.34	\$12.15	\$16.99	\$12.95
Valsartan	\$58.23	\$58.76	\$56.17	\$54.49	\$58.15	\$57.26
Divalproex Sodium	\$136.67	\$113.90	\$149.34	\$126.47	\$136.79	\$115.82
Paroxetine Hcl	\$41.69	\$35.92	\$40.09	\$31.34	\$41.62	\$34.14
Glyburide	\$11.95	\$12.09	\$13.55	\$12.83	\$11.98	\$12.32
Ibuprofen	\$4.04	\$3.99	\$5.99	\$5.53	\$4.06	\$4.21
Nifedipine	\$48.03	\$42.59	\$43.60	\$37.41	\$47.80	\$39.98

Source: Office of Inspector General analysis of 2006 Prescription Drug Event data, 2008.

A P P E N D I X ~ C


**Drugs Most Frequently Involved in Severe and Serious Potential Drug-Drug Interactions**

<b>Table 3: The 20 Drugs Most Frequently Involved in Severe and Serious Potential Drug-Drug Interactions</b>					
<b>Severe</b>			<b>Serious</b>		
<b>Drug Name</b>	<b>Primary Condition Treated</b>	<b>Number of Severe Interactions</b>	<b>Drug Name</b>	<b>Primary Condition Treated</b>	<b>Number of Serious Interactions</b>
Potassium Chloride	Low Potassium Levels	144,778	Warfarin Sodium	Blood Clots	1,016,822
Oxybutynin	Overactive Bladder	50,429	Levothyroxine Sodium	Low Thyroid Levels	385,271
Tolterodine Tartrate	Overactive Bladder	42,813	Potassium Chloride	Low Potassium Levels	363,921
Diphenoxylate Hcl/Atropine Sulfate	Diarrhea	12,608	Clonidine Hcl	High Blood Pressure	346,506
Dicyclomine Hcl	Functional GI Disorders	9,792	Gemfibrozil	High Cholesterol	239,514
Hyoscyamine Sulfate	Functional GI Disorders	7,580	Ciprofloxacin Hcl	Bacterial Infection	197,558
Amiodarone Hcl	Heart Arrhythmias	6,291	Amiodarone Hcl	Heart Arrhythmias	194,097
Selegiline Hcl	Parkinson's Disease	5,805	Triamterene/ Hydrochlorothiazide	Low Potassium Levels	150,336
Benztropine Mesylate	Extrapyramidal Symptoms	5,308	Digoxin	Congestive Heart Failure	144,990
Solifenacin Succinate	Overactive Bladder	4,492	Fenofibrate Nanocrystallized	High Cholesterol	144,374
Darifenacin Hydrobromide	Overactive Bladder	4,310	Tramadol Hcl	Pain	141,729
Disopyramide Phosphate	Heart Arrhythmias	3,698	Atorvastatin Calcium	High Cholesterol	130,171
Thioridazine Hcl	Schizophrenia	2,722	Lovastatin	High Cholesterol	119,036
Ketoconazole	Fungal Infection	2,366	Fluoxetine Hcl	Depression	115,576
Linezolid	Bacterial Infection	1,957	Atenolol	High Blood Pressure	111,713
Ciprofloxacin Hcl	Bacterial Infection	1,912	Metoprolol Tartrate	High Blood Pressure	104,352
Azithromycin	Bacterial Infection	1,877	Sertraline Hcl	Depression	100,254
Trihexyphenidyl Hcl	Parkinsonism	1,835	Spirolactone	High Blood Pressure	98,114
Fluoxetine Hcl	Depression	1,794	Allopurinol	Gout	97,857
Ketorolac Tromethamine	Pain	1,710	Levofloxacin	Bacterial Infections	94,848

Source: Office of Inspector General analysis of 2006 PDE data, 2008.

▶ A P P E N D I X ~ D


Agency Comments

	DEPARTMENT OF HEALTH & HUMAN SERVICES	Centers for Medicare & Medicaid Services
	200 Independence Avenue SW Washington, DC 20201	

**DATE:** NOV 13 2008

**TO:** Daniel R. Levinson  
Inspector General

**FROM:** Kerry Weems  
Acting Administrator 

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "Comparing Special Needs Plan Beneficiaries to Other Medicare Advantage Prescription Drug Plan Beneficiaries" (OEI-05-07-00490)

Thank you for the opportunity to comment on the OIG draft report that compares Special Needs Plan (SNP) beneficiaries to other Medicare Advantage Prescription Drug Plan (MA-PD) beneficiaries with respect to drug utilization, costs, and exposure to potentially inappropriate drug pairs. As expected, the OIG found that SNP enrollees had higher prescription drug costs and utilization than other MA-PD enrollees.

As cited several times in the report, the potential inappropriate drug pairs measured in the report do not track with the actual incidence of adverse drug events. Additionally, the report acknowledges that many of the events that were identified may have been consistent with clinically acceptable prescribing patterns and that without actual provider data it is impossible to draw conclusions about inappropriate prescribing for many of these events.

Eighty-three percent of all of the events identified in the study were classified as moderate under the First Data Bank (FDB) criteria. An additional 16 percent were classified as serious. As indicated in the FDB definitions provided in the report, there are many circumstances when it is clinically appropriate to prescribe drug pairs in these categories. For the remaining 1 percent of events that fell in the severe category the report states that most of these events centered on the use of a few distinct drug pairs that are fairly safely and routinely used together at low doses. In general, the Centers for Medicare & Medicaid Services (CMS) oppose the OIG's selection of FDB as a source for these analyses. FDB's algorithms in the Duplicate Therapy and Drug- Drug Interaction Modules have not been validated for use in the Medicare population.

Most of the identified drug pairs stemmed from prescriptions from the same provider as opposed to prescriptions from multiple providers operating independently. This suggests that appropriate monitoring and assessment of risks may have occurred for many of the events identified in the report. Also, the finding that beneficiaries often had five to six repetitions of the same event in

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the course of the year may indicate that these beneficiaries were stabilized (and likely monitored) on these drug pairs.

Further, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) already requires all Part D sponsors to have concurrent drug utilization review (DUR) systems, policies, and procedures, which ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed. Typically, these DUR systems occur at the point-of-sale or point of distribution.

The Part D sponsors' concurrent DUR programs must include, but are not limited to, the following checks each time a prescription is dispensed:

- Screening for potential drug therapy problems due to therapeutic duplication;
- Age/gender-related contraindications;
- Over-utilization and under-utilization;
- Drug-drug interactions;
- Incorrect drug dosage or duration of drug therapy;
- Drug-allergy contraindications; or
- Clinical abuse/misuse.

That said, CMS believes these DUR requirements ensure a baseline level of patient and drug safety monitoring, as well as support other advancements to further safeguard Medicare beneficiaries.

#### **OIG Recommendation**

The CMS should help SNPs and other MA-PDs provide physicians and pharmacists the information they need to prevent potential inappropriate drug pairs that could lead to Adverse Drug Events (ADEs).

#### **CMS Response**

The CMS concurs with the recommendation to look for ways through which SNPs and other MA-PDs can improve communication with physicians and pharmacists around drug safety. In general, CMS will support efforts that would help safeguard against ADEs as a result of inappropriate drug pairs.

As the OIG points out, e-prescribing is one method to reduce ADEs. Section 101 of the MMA requires Part D sponsors, in accordance with final standards specified by CMS, to establish e-prescribing programs that provide for the electronic transmittal of prescription or prescription-related information to the prescriber or dispenser. This includes information on eligibility, benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization), the drug being prescribed or dispensed and other drugs listed in the medication history, as well as the availability of lower cost and therapeutically appropriate alternatives (if any). Final Part D e-prescribing standards currently exist for (1) transmitting eligibility information between Part D sponsors and prescribers or dispensers, and (2) transmitting prescription or prescription related information between prescribers and

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dispensers. On April 1, 2009, new final standards will become effective that require, among other things, that Part D sponsors support electronic transmission to prescribers of Formulary & Benefit Information and Medication History. CMS issued guidance on September 19, 2008, reiterating the requirement for Part D sponsors to support e-prescribing, particularly with respect to the new standards that become effective April 1, 2009.

While CMS understands that pharmacists and providers may receive a lot of information from sponsors related to various severity levels of drug safety warnings, CMS would not want to discourage plans from forwarding safety-related information to relevant agencies. The U.S. Food and Drug Administration (FDA) Sentinel Project has the specific mandate to augment post-market surveillance of approved medical products. As these efforts may eventually contribute to an understanding of potential risks of drug-drug interactions, the primary focus is to evaluate ADE signals from the Adverse Event Reporting System. The FDA approval process, however, makes provision for defining contraindications of specific drug-drug simultaneous use and these recommendations are the only FDA-approved definitions of specific errors in drug therapy. The FDB algorithm, however, describes drug-drug interactions that may require monitoring within standard of care. Over time, we expect this kind of data to be further refined by the Sentinel Project. CMS believes that the processes and outcomes from the project are the appropriate approach for reducing potential ADEs.

The report also mentions Medication Therapy Management (MTM) programs as a safeguard to reduce ADEs. The report recommends that CMS encourage plans to expand eligibility for MTM services to beneficiaries who fill prescriptions for drugs on the list of drug combinations likely to be involved in severe or serious ADEs. As you know, the statutory goal of the MTM requirements under Part D is to optimize therapeutic outcomes through improved use of Part D medications and to reduce the risks of adverse events.

The CMS has a number of efforts underway to evaluate MTM best practices and raise the level of the education programs offered to Medicare beneficiaries to improve their understanding of the potential risks of prescribed drug combinations and positively impact medication use. This includes evaluating data and best practices to help inform decisions for future Part D MTM program requirements or standards by examining all attributes of MTM programs that may be most effective for the Medicare Program (such as eligibility criteria thresholds, enrollment mechanisms, level of interventions, and outcomes).

#### **Technical Comments**

In the Detailed Methodology section, the following comments apply:

On page 22, the report cites FDB as the source of the Duplicate Therapy module and the Drug-Drug Interaction module. As CMS previously commented at the exit conference on August 26, 2008, although FDB is a widely used commercial database information source, the algorithms within these modules have not been validated for use in the Medicare population. By utilizing this data source, this report could be viewed as validation. Moreover, CMS believes that in the absence of a validated commercially available database, the FDA should be viewed as the primary source of drug information. If the OIG chooses to continue to use FDB as a source for



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this analysis, CMS requests information about FDB's consistency with safety information approved by the FDA.

On page 25, in the report methodology, the definition for therapeutic duplication, which includes three criteria, is not clear. One criterion to define therapeutic duplication, states "(1) two drugs were from the same therapeutic class...", thus it seems that two prescriptions for the same generic drug entity would be identified as therapeutic duplication. It is unclear if prescriptions for brand and generic Zocor would be flagged, or if two prescriptions for different strengths of Zocor would be flagged. In the first example, we believe these could reflect appropriate brand/generic conversion, and the second example could reflect dose titration.

In addition, the report refers to potentially inappropriate drug-drug pairs, but these pairs are not contraindicated by the FDA. Instead, these potential inappropriate drug pairs may indicate the need for monitoring or management by physicians and/or pharmacists.

Finally, at the exit conference on August 26, 2008, CMS staff requested a list of the most common therapeutic duplications. This list was not included in the report.

Again, we thank you for the opportunity to review and comment on this draft report.



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

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Thomas Komaniecki, Deputy Regional Inspector General.

This report was led by Mark Stiglitz. Other principal Office of Evaluation and Inspections staff from the Chicago regional office who contributed include Meghan Kearns and Mara Werner; central office staff who contributed include Doris Jackson, Rita Wurm, and Robert Gibbons.