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**TO:** Donald M. Berwick, M.D.  
Administrator  
Centers for Medicare & Medicaid Services

**FROM:** /S/ Stuart Wright  
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**SUBJECT:** Memorandum Report: *Ensuring That Medicare Part D Reimbursement Is Limited to Drugs Provided for Medically Accepted Indications*, OEI-07-08-00152

This memorandum report provides information about selected Prescription Drug Plan (PDP) sponsors' ability to ensure that Medicare reimbursement for Part D drugs is limited to drugs that are provided for medically accepted indications.

#### SUMMARY

For drugs to qualify for Medicare Part D reimbursement, the *Medicare Benefit Policy Manual* and the *Prescription Drug Benefit Manual* require that they be provided for medically accepted indications. Medically accepted indications include both the uses approved by the Food and Drug Administration (FDA) and off-label<sup>1</sup> uses supported by one or more of three compendia specified in section 1927(g)(1)(B)(i) of the Social Security Act. The Centers for Medicare & Medicaid Services (CMS) charges PDP sponsors with ensuring that Medicare reimbursement for Part D drugs is limited to drugs provided for medically accepted indications.

We found that selected PDP sponsors are unable to systematically ensure that Medicare reimbursement for Part D drugs, including reimbursement for antipsychotic drugs, is limited to drugs provided for medically accepted indications. The issues addressed in this memorandum report arose during the course of an earlier evaluation, entitled *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, OEI-07-08-00150. In that evaluation, we found that 50 percent of Medicare atypical antipsychotic drug claims (amounting to \$116 million) for elderly nursing home residents were erroneous because the claimed drugs were not provided for medically accepted indications as supported by the compendia. This memorandum report provides possible explanations for the high error rate in that evaluation and

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<sup>1</sup> Off-label uses are not approved by FDA and do not appear on drug labels.

provides further support for a prior recommendation that CMS facilitate PDP sponsors' access to information necessary to ensure appropriate reimbursement of Part D claims.

## **BACKGROUND**

Since January 1, 2006, most outpatient prescription drugs for Medicare beneficiaries and dually eligible beneficiaries (beneficiaries eligible for both Medicare and Medicaid) have been covered by the Medicare Part D program. For outpatient drug claims to qualify for Medicare Part D reimbursement, the drugs must be provided for medically accepted indications. Medically accepted indications include both uses approved by FDA and uses supported by one or more of three compendia specified in section 1927(g)(1)(B)(i) of the Social Security Act. The three compendia, hereinafter referred to collectively as the compendia, are the (1) American Hospital Formulary Service Drug Information (AHFS-DI), (2) United States Pharmacopeia-Drug Information (or its successor publications) (USP-DI), and (3) DrugDEX Information System (DrugDEX).

### **CMS Requirements for PDP sponsors**

PDP sponsors must establish a comprehensive fraud and abuse plan to detect, correct, and prevent fraud and abuse as part of a compliance plan.<sup>2</sup> Payments for Part D drugs that are not for medically accepted indications are considered potential fraud or abuse. PDP sponsors may use various strategies to ensure that Part D drug payments are limited to drugs provided for medically accepted indications. The *Prescription Drug Benefit Manual* does not provide any examples of such strategies. PDP sponsors may rely on strategies such as prepayment edits, prior authorization, and postpayment reviews. However, many of these strategies depend on information that is not required for Part D claims;<sup>3</sup> therefore, PDP sponsors would need to collect information currently not included on claims.

*Prepayment strategies.* Prepayment strategies, such as prepayment edits and prior authorization, allow PDP sponsors to prevent inappropriate payments for drugs. Prepayment edits could prevent payments for drugs that are not provided for medically accepted indications. The *Prescription Drug Benefit Manual* does not provide any specific examples of how PDP sponsors could use prepayment edits. However, one approach could be to require diagnosis information that would match the beneficiary's diagnosis against the medically accepted indications listed in the compendia prior to distribution at the point of sale.

PDP sponsors may also use prior authorization as a prepayment strategy. Prior authorization requires additional information from a prescriber before a PDP sponsor approves payment for a particular drug. Prior authorization helps to ensure that particular drugs are used correctly and

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<sup>2</sup> Chapter 9 of the *Prescription Drug Benefit Manual* provides interpretive rules and guidance for PDP sponsors on how to implement the regulatory requirements under 42 CFR § 423.504(b)(4)(vi)(H) to establish a comprehensive fraud and abuse plan. For this memorandum report, we did not review PDP sponsors' comprehensive fraud and abuse plans. CMS, *Prescription Drug Benefit Manual* (Internet-Only Manual), Pub. No. 100-18, ch. 9.

<sup>3</sup> CMS, *Instructions: Requirements for Submitting Prescription Drug Event Data*, April 26, 2006. Diagnosis codes are not required data elements of prescription drug event data.

only when necessary.<sup>4</sup> However, in most instances the use of prior authorization is prohibited for six protected classes of drugs, including antipsychotic drugs.<sup>5, 6</sup>

*Postpayment strategies.* Rather than preventing payments for drugs not provided for medically accepted indications, postpayment review allows PDP sponsors to detect these payments after they occur. The *Prescription Drug Benefit Manual* does not provide any specific examples of how PDP sponsors could use postpayment reviews. PDP sponsors could collect diagnosis information and/or medical records from the prescribing physician to retrospectively compare beneficiary diagnosis to medically accepted indications. This would enable PDP sponsors to recoup payment for drugs that are not provided for medically accepted indications.

### **Compendia**

Each of the three compendia identified in the Social Security Act is a comprehensive source for medically accepted indications of drugs. However, the off-label uses supported by each compendium can differ. For example, DrugDEX supports more off-label uses for atypical antipsychotic drugs than AHFS-DI and USP-DI. Only one compendium needs to support an off-label use for that use to meet the medically accepted indications requirement for Medicare Part D reimbursement.

The compendia are updated at different intervals and in different formats. AHFS-DI and USP-DI are published annually in hardcopy formats. DrugDEX is updated quarterly in an electronic format. The quarterly updates replace older versions.<sup>7</sup> Subscribers to DrugDEX have access to only the most recent quarterly version, meaning that claims for drugs would need to be submitted and payment reviews would need to occur in the same quarter as the drugs were provided to ensure payments are appropriate.<sup>8</sup>

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<sup>4</sup> CMS, *Physician Part D Resource Fact Sheet*. Accessed at [https://www.cms.gov/MLNProducts/downloads/transitional\\_toolkit\\_revised.pdf](https://www.cms.gov/MLNProducts/downloads/transitional_toolkit_revised.pdf) on July 18, 2011.

<sup>5</sup> 74 Fed. Reg. 2882 (Jan. 16, 2009).

<sup>6</sup> These drug classes are protected to ensure that Medicare beneficiaries are not discouraged from enrolling in certain Part D plans, and to minimize the risks and complications associated with an interruption in drug therapy. PDP sponsors may use prior authorization for drugs in the six protected classes only when a beneficiary is being prescribed such a drug for the first time. PDP sponsors are prohibited from using prior authorization for those beneficiaries already enrolled in the plan and currently taking a drug in any protected class. Further, PDP sponsors may not implement prior authorization if it is intended to steer beneficiaries who are currently taking a drug within the protected classes to preferred alternative drugs. CMS, *Prescription Drug Benefit Manual* (Internet-Only Manual), Pub. No. 100-18, ch. 6, § 30.2.5.

<sup>7</sup> For any drug, medically accepted indications can be added or removed from DrugDEX during a quarterly update as peer-reviewed research supports new uses for drugs and/or refutes previously accepted uses. The frequency with which medically accepted indications for drugs were either added or removed from DrugDEX from one quarter to the next was outside the scope of this memorandum report.

<sup>8</sup> Subscribers can create a hardcopy of the most recent quarterly version by printing the compendium or save it to a file for future use. However, subscribers would need to diligently print or save each new quarterly version to ensure that the accurate version of DrugDEX was used.

### **Previous OIG Work**

In our previous evaluation, entitled *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* (OEI-07-08-00150), we found that half of Medicare Part D claims for atypical antipsychotic drugs received by elderly nursing home residents from January 1 through June 30, 2007, were erroneous because the claimed drugs were not provided for medically accepted indications as supported by the compendia published closest to the review period. For that evaluation, we obtained the 2007 versions of AHFS-DI and USP-DI. We also sought the first two quarters of DrugDEX for 2007, but CMS was unable to provide them. We attempted to locate this compendium information through other sources, including FDA, the National Institutes of Health, and the Library of Congress, but were unsuccessful. Therefore, we used a printed version of the first-quarter 2008 DrugDEX we had created at the start of our study. We checked the compendia to determine whether atypical antipsychotic drug claims complied with Medicare reimbursement criteria regarding medically accepted indications.

### **METHODOLOGY**

Because we found that half of Medicare Part D claims for atypical antipsychotic drugs received by elderly nursing home residents in the first 6 months of 2007 were erroneous, we were interested in identifying strategies that PDP sponsors use to ensure that Part D payments for drugs are limited to those that are provided for medically accepted indications. Because we were unable to obtain the first two quarters of DrugDEX for 2007, we were also interested in determining to what extent PDP sponsors had access to all compendia.

#### **Scope**

We interviewed three PDP sponsors representing more than 30 percent of the beneficiaries enrolled in Part D plans for 2011. We did not assess the completeness or accuracy of these sponsors' compliance plans or comprehensive fraud and abuse plans.

Because CMS has charged PDP sponsors with ensuring that Medicare reimbursement for Part D drugs is limited to drugs provided for medically accepted indications, we focused our data collection on PDP sponsors' reported strategies for ensuring that drugs are provided appropriately. Therefore, we did not determine whether CMS conducts oversight of PDP sponsors' compliance plans or has its own processes for conducting payment reviews of Part D claims, or the frequency of any such reviews.

#### **Sample Selection**

We identified three large PDP sponsors with at least 900,000 enrollees for 2011 using publicly available Part D enrollment data.

#### **Drug Plan Sponsor Interviews**

We interviewed the three large PDP sponsors to identify the strategies they use to ensure that Medicare reimbursement for Part D drugs is limited to drugs provided for medically accepted indications. Specifically, we asked the PDP sponsors whether they collect diagnosis information for drug claims; whether they use prepayment edits, prior authorization, and/or postpayment review to identify noncompendium payments; whether they have additional safeguards in their

fraud and abuse plans to ensure that drugs are provided only for medically accepted indications; and whether they have access to historical DrugDEX information for conducting postpayment review.

### **Limitations**

The PDP sponsors we interviewed are not representative of all PDP sponsors; however, they represent more than 30 percent of the beneficiaries enrolled in Part D plans.

### **Standards**

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

## **RESULT**

### **All Three Selected PDP Sponsors Lack Access to Information Necessary for Appropriate Reimbursement of Part D Drugs**

PDP sponsors are unable to systematically ensure that payments for Part D drugs are limited to drugs provided for medically accepted indications.

*Prepayment strategies are limited.* The three PDP sponsors we interviewed reported that they do not routinely collect diagnosis information because CMS does not require diagnoses as a data element for Part D claims. PDP sponsors do not collect related diagnoses for Part D claims from pharmacies because it is not standard practice for prescribers to provide the diagnoses. Unless diagnosis information is required and included on a Part D claim, determining whether a drug was provided for a medically accepted indication, and therefore was reimbursable by Medicare, is not possible using claims data alone.

All three PDP sponsors reported that they do not routinely collect diagnosis information, except when using prior authorization. The PDP sponsors indicated that prior authorization is the best tool they currently have to compare the diagnosis provided by the prescriber to the medically accepted indications contained in the compendia. One PDP sponsor stated that it has had great success at preventing payments for drugs not provided for medically accepted indications by using prior authorization when permitted.

However, according to the selected PDP sponsors, CMS's prior authorization policy limits PDP sponsors' use of prior authorization for antipsychotic drugs. Because antipsychotics are one of the six protected drug classes, the PDP sponsors indicated that they use prior authorization for antipsychotics only in limited circumstances. Specifically, PDP sponsors reported that they use prior authorization only the first time a beneficiary is prescribed an antipsychotic drug. PDP sponsors reported that they do not use prior authorization when beneficiaries enroll who are already using antipsychotic drugs or if the beneficiary receives subsequent prescriptions for the antipsychotic drug.

*Postpayment reviews do not focus on medically accepted indications.* All three PDP sponsors reported using postpayment review as a general safeguard to prevent fraud and abuse. However,

all three PDP sponsors indicated that these reviews do not commonly focus on medically accepted indications. The three PDP sponsors reported that they have real-time access to all compendia, but do not have historical access to DrugDEX. Because DrugDEX is updated and published quarterly, it is possible that information about a particular drug may be updated between the time a drug is provided and the time payment review is conducted. To ensure that the correct DrugDEX information was used, claims for Part D drugs would need to be submitted and payment review conducted in the same quarter as the drugs were provided.

## **CONCLUSION**

In our previous evaluation, we found that 50 percent of Medicare Part D claims for atypical antipsychotic drugs received by elderly nursing home residents from January 1 through June 30, 2007, were erroneous because the claimed drugs were not provided for medically accepted indications as supported by the compendia. This memorandum report provides possible explanations for that high error rate. PDP sponsors lack the diagnosis information necessary to systematically ensure that payments for Part D drugs, including antipsychotic drugs, are limited to those provided for medically accepted indications. PDP sponsors reported that they use prior authorization only in certain circumstances for certain drug classes to ensure that reimbursement for Part D drugs is limited to drugs provided for medically accepted indications. Further, PDP sponsors' postpayment reviews do not focus on ensuring that payments for drugs are limited to those provided for medically accepted indications. Finally, PDP sponsors lack access to historical compendia information necessary to determine whether drugs were provided for medically accepted indications during their reviews.

In our previous evaluation, we recommended that CMS facilitate PDP sponsors' access to information necessary to ensure accurate reimbursement of Part D claims. CMS did not concur with this recommendation. This memorandum report provides further evidence to support the prior recommendation. We continue to encourage CMS to work with PDP sponsors to improve the appropriateness of Part D reimbursement. We will continue to monitor the accuracy of Part D payments, as it affects not only atypical antipsychotic drugs, but all Part D drugs.

## **AGENCY COMMENTS AND OIG RESPONSE**

CMS stated that it does not have statutory authority to require physicians to include diagnosis information on prescriptions, which are generally governed by State law. Absent diagnosis information, pharmacies would be unable to comply with a requirement to include diagnoses on claims submitted to PDP sponsors. Moreover, CMS indicated that it is not convinced that the solution to inappropriate drug use lies with the PDP sponsors' utilization management tools, including prior authorization. CMS stated that prior authorization can be costly and burdensome. CMS further stated that the current approach, which permits PDP sponsors to use prior authorization to target drugs that are at high risk for being prescribed without a medically accepted indication, is the appropriate balance to control PDP sponsors' costs and additional burdens that excessive use of prior authorization would place on pharmacies, prescribers, and beneficiaries of Part D drugs.

We did not make any changes to the report based on CMS's comments. For the full text of CMS's comments, please see the Attachment.

This evaluation is being issued directly in final form because it contains no recommendations. If you have any questions or additional comments about the report, please provide them within 60 days. To facilitate identification, please refer to memorandum report number OEI-07-08-00152 in all correspondence.

Attachment:  
CMS comments regarding the memorandum report



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

*Administrator*  
Washington, DC 20201

**DATE:** OCT - 7 2011

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

**FROM:** Donald M. Berwick, M.D. */S/*  
Administrator

**SUBJECT:** Office of Inspector General's (OIG) Memorandum Report: "Ensuring that Medicare Part D Reimbursement Is Limited to Drugs Provided for Medically Accepted Indications" (OEI-07-08-00152)

Thank you for the opportunity to review and comment on the subject memorandum report titled: *Ensuring that Medicare Part D Reimbursement is Limited to Drugs Provided for Medically Accepted Indications* (OEI-07-08-00152). In this memorandum report, the OIG concludes that Prescription Drug Plan (PDP) sponsors lack the diagnosis information necessary to determine whether the drug has been prescribed for a medically accepted indication and for systematically ensuring that payments for Part D drugs, including antipsychotic drugs, are permissible.

The OIG indicates that the three PDP sponsors interviewed reported that they do not routinely collect diagnosis information because the Center for Medicare & Medicaid Services (CMS) does not require diagnoses for Part D claims from pharmacies because it is not standard practice for prescribers to provide the diagnoses. OIG concludes that without the diagnosis, sponsors have difficulty preventing payments for drugs not provided for medically accepted indications on the basis of claims data alone. OIG also notes that prior authorization is not permitted for all prescriptions in the six protected classes in most instances, that the interviewed sponsors do not focus post-payment reviews for medically-accepted indications, and that sponsors do not have historical access to the DrugDEX compendia.

As the OIG stated in this report, the current industry standard for point-of-sale claims adjudication does not require diagnosis information be provided as part of the claim. Additionally, diagnosis information isn't readily available on the prescription written by the prescriber. CMS does not have the statutory authority to require physicians to include diagnosis information on prescriptions, which are generally governed by state law. Absent diagnosis information on the prescription, pharmacies would have no ability to comply with a requirement to include diagnoses on the claims submitted to Part D sponsors. Furthermore, even if diagnosis information were available on both the prescription and the claim, sponsors may not be able to ascertain that the prescribed drug was used for a medically accepted indication using current coding standards. For example, the drug Zelboraf (vemurafenib) is only on-label, on-compendia

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for a specific type of melanoma (BRAF V6003 mutation positive). The diagnosis information would not be detailed enough to determine whether the patient has a BRAF V6003 mutation, as the International Classification of Diseases (ICD10) does not specify that level of granularity (e.g., ICD10 for malignant melanoma of trunk is C43.5). Thus the medically-accepted indication in the compendia may rely on information below the level of coding in ICD10 (as is the case with atypical antipsychotics).

Moreover, CMS is not convinced that the entire solution to inappropriate drug use lies with the Part D sponsors' utilization management programs. Using utilization management tools such as prior authorization can be costly to the Part D sponsor and applying this tool excessively will place a significant additional burden on the pharmacy, prescriber, and beneficiary, including delaying therapies critical to maintaining the patient's health. We believe our current approach which permits plan sponsors to use prior authorization to target drugs that are at high risk for prescribing without a medically accepted indication is the appropriate balance.

Part D sponsors may retrospectively identify and confirm – either as part of their retrospective review programs required under 42 CFR 423.153, or incident to another utilization management review – that a dispensed drug was not prescribed for a medically-accepted indication for a particular individual. Although Part D sponsors have this tool, the retrospective review wouldn't solve the atypical antipsychotic issue, because the compendia reference is to dementia-related behaviors and is a very inclusive indication that would likely be present in patient medical records in most cases.

The OIG also reiterated their previous recommendation for CMS to facilitate Part D sponsors' access to information necessary to ensure accurate reimbursement. CMS would like to note CMS cannot distribute compendia information as they are commercially licensed products and that would be a violation of the licensing agreement.

The CMS shares the OIG's concern related to ensuring that we only reimburse sponsors for permissible Part D drugs. However, as we stated in our earlier response to the OIG's "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents" (OEI-07-08-00150), the number of erroneous payments cited in that study was grossly inflated due to the exclusion of dementia as a medically accepted indication for certain atypical antipsychotics. We continue to believe this is a quality of care issue that is better addressed at the prescriber level. CMS is working with prescribers and Part D sponsors to improve overall quality of care, to ensure compliance with statutory and manual requirements, and to implement industry best practices without impeding access to care.

Thank you for the opportunity to review and comment on the memorandum report.