

Department of Health & Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE PRESCRIPTION DRUG  
SPONSORS' TRAINING TO  
PREVENT FRAUD, WASTE,  
AND ABUSE**



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## OBJECTIVES

1. To determine the extent to which Medicare drug plan sponsors provided, and network pharmacies took, training to prevent fraud, waste, and abuse in 2009.
2. To determine the extent to which the training's content reflected Centers for Medicare & Medicaid Services' (CMS) guidance.
3. To describe the extent to which plan sponsors determined that the training was effective.

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## BACKGROUND

Medicare Part D provides prescription drug coverage to beneficiaries through private plan sponsors that contract with CMS. Sponsors provide drug coverage through either a stand-alone prescription drug plan or a Medicare Advantage prescription drug plan.

As a condition for contracting with CMS to offer Part D benefits, sponsors must have compliance plans that help them follow Federal regulations and prevent fraud, waste, and abuse. Among other elements that CMS requires, these plans must include effective annual training and education to prevent fraud, waste, and abuse for network pharmacies. Office of Inspector General reviews of Medicare prescription drug plans and reports in the news media have shown that pharmacies are at risk for fraud, waste, and abuse from beneficiaries, employees, prescribers, and drug manufacturers. This raises concerns about the extent to which sponsors comply with these requirements.

To conduct this study, we surveyed all 266 Part D sponsors and a random sample of 528 pharmacies (165 chain pharmacies, 157 independent pharmacies, and 206 mail-order pharmacies) to collect data on training to prevent fraud, waste, and abuse in 2009. We also analyzed 420 training materials from sponsors and pharmacies. Finally, we interviewed a purposive sample of five sponsors and five pharmacies based on their survey responses.

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## FINDINGS

**Nearly all Part D network pharmacies received training to prevent fraud, waste, and abuse in 2009; however, not all sponsors documented the training.** At least 87 percent of pharmacies reported that all of their staff received training. However, 30 percent of sponsors

did not require their network pharmacies to submit documentation of training to verify completion.

**Training materials generally reflected CMS guidance on content and source, with a few exceptions.** Although most training materials included all elements in CMS guidance, more than a third failed to include information on the Health Insurance Portability and Accountability Act (HIPAA). Additionally, more than half of the materials were developed by pharmacies' corporate offices, despite CMS guidance to sponsors stating that pharmacies should not develop their own materials.

**Most sponsors could not determine the extent to which training was effective.** Although 59 percent of sponsors reported that they assessed the training's effectiveness, fewer than half could measure its impact on fraud, waste, and abuse. The remaining 41 percent did not assess its effectiveness.

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## RECOMMENDATIONS

Fraud, waste, and abuse represent significant threats to Medicare Part D, making training on how to prevent them vital to safeguarding the program. Toward that end, CMS provided guidance on such training to strengthen network pharmacies' ability to prevent, detect, and respond to these threats. This study identified opportunities to help hone the effectiveness of that training.

Therefore, we recommend that CMS:

**Reiterate to sponsors their responsibilities as the entities accountable for network pharmacies' training to prevent Part D fraud, waste, and abuse.** CMS should reissue guidance to sponsors regarding its expectations for them to: (1) develop and disseminate training materials to their network pharmacies; (2) include HIPAA in their training materials; (3) maintain documentation that pharmacies have received training; and (4) determine the extent to which they are providing effective training and education that reduce fraud, waste, and abuse risks.

**Use its monitoring authority to determine compliance with training requirements.** CMS routinely audits sponsors' compliance plans to oversee sponsors' adherence to programmatic requirements. Toward that end, CMS should use these audits to ensure that sponsors are in compliance with all fraud, waste, and abuse training requirements noted above. To achieve this goal, CMS should: (1) review training materials to

ensure that pharmacies are not developing them; (2) verify that all required contents, including HIPAA, are part of the materials; (3) clarify its requirements regarding sponsors' obligations to collect documentation from their network pharmacies that they have taken training; and (4) request documentation supporting the extent to which sponsors are developing and providing effective training and education for their network pharmacies.

**Take steps to ensure that sponsors are providing effective training and education to prevent fraud, waste, and abuse.** CMS requires sponsors to provide their network pharmacies with training and education that are effective in preventing, detecting, and responding to potential fraud, waste, and abuse. Therefore, CMS should: (1) develop guidance for sponsors to use in assessing the effectiveness of training and education on fraud, waste, and abuse; or (2) provide a forum (e.g., online or conference call) in which sponsors can share best practices used to determine the training's effectiveness.

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendations.

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## BACKGROUND

Medicare Part D provides prescription drug coverage to beneficiaries through private plan sponsors that contract with CMS. Sponsors provide drug coverage through either a stand-alone prescription drug plan or a Medicare Advantage prescription drug plan.<sup>1</sup> In 2009, 266 sponsors offered Part D plans.

Previous Office of Inspector General (OIG) reviews of Medicare prescription drug plans and reports in the news media indicate that pharmacies are at risk for fraud, waste, and abuse from beneficiaries, employees, prescribers, and drug manufacturers.<sup>2, 3, 4</sup> Although CMS requires Part D sponsors to develop compliance programs that provide their network pharmacies with training to prevent fraud, waste, and abuse, OIG and the Government Accountability Office (GAO) have shown that CMS has not sufficiently audited sponsors' compliance plans to determine whether pharmacies' staff can prevent, detect, and respond to fraud, waste, and abuse.<sup>5, 6</sup> The vulnerabilities identified within pharmacies raise concerns about the extent to which sponsors have

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<sup>1</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173, § 101; Social Security Act, § 1860D-1(a); 42 U.S.C. § 1395w-101(a).

<sup>2</sup> OIG, *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse*, OEI-03-07-00380, October 2008.

<sup>3</sup> Associated Press, *Grand Coueteau Pharmacist Pleads Guilty*, December 19, 2009. Accessed at [www.wdam.com](http://www.wdam.com) on December 22, 2009.

<sup>4</sup> E. White, *Meijer Will Settle Pharmacy Case for \$3 Million*, Associated Press, December 8, 2009. Accessed at [www.abcnnews.go.com](http://www.abcnnews.go.com) on December 22, 2009.

<sup>5</sup> OIG, *Oversight of Prescription Drug Plan Sponsors' Compliance Plans*, OEI-03-08-00230, October 2008.

<sup>6</sup> GAO, *Some Plan Sponsors Have Not Completely Implemented Fraud and Abuse Programs, and CMS Oversight Has Been Limited*, GAO-08-760, July 2008.

complied with CMS's requirement to provide effective training and whether fraud, waste, and abuse may be undetected in a pharmacy setting.

### **Medicare Part D Compliance Plans**

As a condition for contracting with CMS to offer Part D benefits, sponsors must have in place compliance plans that help them follow Federal regulations and prevent fraud, waste, and abuse. Each plan must include the following elements:

- written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards;
- the designation of a compliance officer and compliance committee accountable to senior management;
- provision of effective training and education by the compliance officer and the sponsor's employees, managers, and directors for the sponsor's first-tier, downstream, and related entities;
- effective lines of communication between (1) the compliance officer, members of the compliance committee, the sponsor's employees, managers, and directors; and (2) the sponsor's first-tier, downstream, and related entities;
- enforcement of standards through well-publicized disciplinary guidelines;
- procedures for effective internal monitoring and auditing; and
- procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as a sponsor.<sup>7</sup>

### **CMS's Requirement for Sponsors To Provide Effective Training and Education To Prevent Fraud, Waste, and Abuse**

CMS requires sponsors' compliance plans to provide for effective training and education to first-tier, downstream, and related entities.<sup>8</sup> A first-tier entity is any party that enters into a contract with a sponsor, such as a pharmacy benefit manager (PBM). A downstream entity is

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<sup>7</sup> 42 CFR § 423.504(b)(4)(vi). CMS revised its compliance program regulations in 2010 to provide more detail generally with respect to each of the program elements, including the requirement for training. 75 Fed. Reg. 19678 (Apr. 15, 2010).

<sup>8</sup> Ibid.

any party that enters into a written arrangement with a sponsor and first-tier entity, such as a network pharmacy. Network pharmacies include retail, mail-order, long-term-care, home infusion, and Indian Health Services/Tribal/Urban Indian Health (I/T/U) pharmacies.<sup>9</sup> A related entity is any party related to a sponsor by common ownership or control, such as a PBM whose parent company is a sponsor.<sup>10</sup> Because sponsors rely specifically on network pharmacies and pharmacists to administer Part D benefits, sponsors must provide them with effective training on how to prevent, detect, and respond to fraud, waste, and abuse.

Medicare regulations state that sponsors must provide effective training and education on fraud, waste, and abuse.<sup>11</sup> However, CMS does not provide any specific definition of what constitutes effective training and education. Therefore, it is the sponsors' responsibility to determine whether the training and education they provide to their network pharmacies are effective in preventing fraud, waste, and abuse.

#### **CMS Guidance on Training To Prevent Fraud, Waste, and Abuse**

In 2008, CMS clarified its guidance on training and education to prevent fraud, waste, and abuse and set deadlines for sponsors to provide training to network pharmacies and downstream and related entities. This guidance required sponsors to provide training between January 1 and December 31, 2009, and annually thereafter.<sup>12</sup>

Since Part D began, sponsors have sought clarification from CMS on the content of fraud, waste, and abuse training and have raised concerns about how to provide it to their network pharmacies.<sup>13</sup> Although CMS offers general recommendations on the content of training and education, it does not specify a complete list of elements that must be included.<sup>14</sup> For example, CMS states that training and education

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<sup>9</sup> Home infusion pharmacies provide medications to beneficiaries who need long-term therapy while living at home.

<sup>10</sup> 42 CFR § 423.501.

<sup>11</sup> 42 CFR § 423.504(b)(4)(vi).

<sup>12</sup> CMS Memorandum, *Fraud, Waste and Abuse Training Requirements*, October 20, 2008.

<sup>13</sup> Ibid.

<sup>14</sup> CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 9, § 50.2.3.1; CMS Memorandum, *Fraud, Waste and Abuse Training Clarification*, August 21, 2009.

should include, but not be limited to, the following topics for all first-tier, downstream, and related entities:<sup>15</sup>

- laws and regulations related to Part D fraud, waste, and abuse (i.e., False Claims Act, antikickback statute, Health Insurance Portability and Accountability Act (HIPAA));
- obligations to have appropriate policies and procedures to address fraud, waste, and abuse;
- process for reporting suspected fraud, waste, and abuse to the sponsor;
- protections for employees who report suspected fraud, waste, and abuse; and
- types of fraud, waste, and abuse that can occur.<sup>16</sup>

CMS allows sponsors to delegate the development of training materials and the administration of training to any contractor, such as a PBM, professional association, or third-party consultant. CMS guidance to sponsors states that pharmacies should not develop their own training materials, as this is the sponsors' responsibility.<sup>17, 18</sup> However, CMS guidance states that pharmacy staff may administer the training to themselves if the materials are provided by a sponsor or contractor.

CMS gives sponsors latitude in how training is administered. The agency's guidance states that "training can be conducted interactively, led by expert facilitators, via Web-based tools and Intranet sites, live or videotaped presentations, written materials, or a combination of these techniques."<sup>19</sup> To assist sponsors in developing training, CMS guidance identifies types of fraud, waste, and abuse risks that may occur in a pharmacy setting:

- billing for nonexistent prescriptions;

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<sup>15</sup> CMS uses the term "should" for recommendations, but uses "shall" or "must" to refer to statutory or regulatory program requirements.

<sup>16</sup> CMS Memorandum, *Fraud, Waste, and Abuse Training Clarification*, August 21, 2009.

<sup>17</sup> CMS Memorandum, *Fraud, Waste, and Abuse Training Requirements*, October 20, 2008.

<sup>18</sup> A PBM may provide training materials to its own pharmacies on behalf of sponsors with which it contracts. However, pharmacies' corporate offices that are not acting as PBMs should not provide training materials.

<sup>19</sup> CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 9, § 50.2.3.3.

- billing for more expensive brand-name drugs but dispensing generics;
- forging or altering prescriptions;
- switching, splitting, or shorting prescriptions; and
- stealing a Medicare beneficiary's identity.<sup>20</sup>

### **Sponsors' Obligations To Provide or Ensure Provision of Training**

CMS requires sponsors to either provide training directly to all of their pharmacies or to provide training materials and ensure that the training has been taken.<sup>21</sup> CMS guidance does not specify how sponsors should ensure that their network pharmacies have taken training to prevent fraud, waste, and abuse; however, CMS states that as part of an audit and review process, it will verify that all necessary training has been provided.<sup>22</sup>

Sponsors contend that it is cumbersome for pharmacies to receive training from each sponsor with which they contract.<sup>23, 24</sup> Therefore, CMS states that network pharmacies need to take only one training that fulfills the requirement and provide proof to each sponsor to verify completion.<sup>25, 26</sup>

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## **METHODOLOGY**

### **Scope**

This study analyzed the extent to which Medicare drug plan sponsors provided, and network pharmacies received, training to prevent fraud, waste, and abuse in 2009. It also analyzed the extent to which sponsors determined whether training was effective in preventing, detecting, and responding to these threats. Although training should be provided to all first-tier, downstream, and related entities, this study focused on network pharmacies only—specifically, chain, independent, and mail-order pharmacies. This study excluded long-term-care, home

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<sup>20</sup> CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 9, § 70.1.3.

<sup>21</sup> CMS Memorandum, *Fraud, Waste, and Abuse Training Requirements*, October 20, 2008.

<sup>22</sup> 72 Fed. Reg. 68700, 68707 (Dec. 5, 2007).

<sup>23</sup> CMS Memorandum, *Fraud, Waste, and Abuse Training Clarification*, August 21, 2009.

<sup>24</sup> 74 Fed. Reg. 54644 (Oct. 22, 2009).

<sup>25</sup> *Ibid.*

<sup>26</sup> 72 Fed. Reg. 68706 (Dec. 5, 2007).

infusion, and I/T/U pharmacies because they make up a small percentage of the population of network pharmacies. This study focused specifically on the elements of sponsors' training that address Part D fraud, waste, and abuse. We did not review other elements of sponsors' compliance plans, nor did we assess sponsors' overall program compliance.

### **Data Sources**

We used the following four data sources to analyze training to prevent fraud, waste, and abuse in 2009: (1) a survey of Part D sponsors, (2) a survey of a random sample of network pharmacies, (3) training materials, and (4) followup interviews with sponsors and pharmacies.

*Survey of Part D sponsors.* We surveyed all 266 sponsors that offered Part D plans in 2009. We used files from CMS's Health Plan Management System to create the universe of sponsors. We developed and used a questionnaire to determine the extent to which sponsors developed and provided training in 2009. We also used the questionnaire to ask sponsors for contextual information, such as who designed the training and what documentation they used to verify that network pharmacies had taken it. Additionally, we used the questionnaires to assess how sponsors determine whether their network pharmacies are receiving training and education that are effective in preventing, detecting, and responding to fraud, waste, and abuse. We made three attempts to obtain survey responses from sponsors. We made the first attempt via U.S. Postal Service, the second attempt by UPS, and the third attempt by phone. We received responses from 258 sponsors, a response rate of 97 percent.

*Survey of random sample of network pharmacies.* We surveyed a random sample of 528 pharmacies. We used files from the National Council of Prescription Drug Programs (NCPDP), which contains a list of all pharmacies in the United States, to create the universe of pharmacies, which contained 75,675 pharmacies.

We limited the file to nongovernment retail and mail-order pharmacies that opened prior to November 1, 2009.<sup>27, 28</sup> This resulted in 61,003 pharmacies from which to select our sample. After excluding pharmacies in our pretest sample and duplicate pharmacies in the

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<sup>27</sup> We excluded long-term-care, home infusion, and I/T/U pharmacies.

<sup>28</sup> We selected 15 pharmacies to pretest our survey prior to drawing our random sample.

NCPDP list, this left 60,786 pharmacies (40,086 chain, 20,479 independent, and 221 mail-order) from which to select our sample.

We divided our pharmacy population into three strata: chain retail pharmacies, independent retail pharmacies, and mail-order pharmacies. Our total sample included 551 pharmacies: random samples of 165 chain retail pharmacies and 165 independent retail pharmacies and the complete population of 221 mail-order pharmacies.<sup>29</sup> We dropped 23 pharmacies (8 independent pharmacies and 15 mail-order pharmacies) that responded to our questionnaire that they were either no longer in business or did not submit Part D claims in 2009, which reduced our total sample size to 528.

In our questionnaire, we also asked pharmacies for contextual information, such as whether their training was provided to them by sponsors, industry associations, or other sources or was self-administered. We used these questionnaires to determine the extent to which network pharmacies took training to prevent fraud, waste, and abuse in 2009 and which organization developed and administered it.

We made three attempts to obtain survey responses from pharmacies. We sent the first two attempts via U.S. Postal Service and the third attempt via UPS. Our overall response rate was 74 percent.<sup>30</sup> We received 335 survey responses: 113 chain pharmacies, 136 independent pharmacies, and 86 mail-order pharmacies responded. Because the NCPDP data lacked information about pharmacy characteristics, we were unable to compare respondents to nonrespondents.

***Training materials.*** Our questionnaire asked sponsors and pharmacies to submit copies of any materials they used in 2009 to conduct training to prevent fraud, waste, and abuse. Among the 258 sponsor respondents, 209 (81 percent) submitted materials. We received materials from 211 pharmacies. This represents 38 percent of the 551 pharmacies surveyed and 63 percent of the 335 pharmacy respondents. We used these materials to assess the extent to which sponsors followed CMS guidance on training material content.

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<sup>29</sup> NCPDP defines chain pharmacies as a group of four or more pharmacies under common ownership; independent pharmacies may have one to three pharmacies under common ownership.

<sup>30</sup> This calculation was weighted based on the stratified sample selection.

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

*Followup interviews with sponsors and pharmacies.* We interviewed staff from a purposive sample of five sponsors and five pharmacies. We selected each interviewee based on responses to our survey. We aimed to interview sponsors and pharmacies whose responses were substantively different from one another. We asked sponsor staff about the process they use to create and conduct training and the way in which they ensure that network pharmacies comply with training requirements. In addition, we asked how they evaluate the effectiveness of training and requested any documentation that supports this. Similarly, we asked pharmacy staff about their experiences with and perceptions of training to prevent fraud, waste, and abuse. We analyzed interview data for common themes.

### **Limitations**

All data from surveys are self-reported. We did not independently verify survey responses or information given in interviews.

### **Standards**

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

## ► FINDINGS

### **Nearly all Part D network pharmacies received training to prevent fraud, waste, and abuse in 2009; however, not all sponsors documented the training**

CMS requires sponsors to provide training to prevent fraud, waste, and abuse for any pharmacy employee responsible

for delivering Part D benefits. CMS has also stated that it will audit sponsors to determine whether the training requirements have been met.<sup>31</sup>

### **At least 87 percent of pharmacies reported that all of their staff received training in 2009**

Most pharmacies reported that every staff member involved in delivering the Part D benefit—such as pharmacists, pharmacy managers, and pharmacy technicians—took training. One to two percent of pharmacies indicated that only some of the required staff took training. Table 1 shows the percentage of pharmacy staff who received training. (See Appendix A for complete point estimates and confidence intervals of pharmacy data.)

Table 1: Rates of Training To Prevent Fraud, Waste, and Abuse for Pharmacy Employees

Pharmacy Staff Who Received Training	Pharmacies Reporting That All Staff Received Training (n=335)	Pharmacies Reporting That Most or Some Staff Received Training (n=335)
Pharmacists	95%	1%
Pharmacy managers	88%	0%
Pharmacy technicians	90%	2%

Rows do not sum to 100% because not all pharmacies employ each type of pharmacy staff listed above.

Source: OIG survey of Part D network pharmacies, 2010.

Overall, pharmacies reported that staff took training either individually or as a combination of group and individual training. Pharmacies also reported that the format of their training included a computer-assisted component and written materials. Fewer pharmacies reported that their training included lecture and discussion.

<sup>31</sup> 72 Fed. Reg. 68700, 68707 (Dec. 5, 2007).

**Sponsors did not always require their network pharmacies to submit documentation of training**

Thirty percent of sponsors reported that they did not require documentation showing that pharmacy staff had taken training. Similarly, 35 percent of pharmacies reported that sponsors did not require them to submit documentation verifying completion of the training. Sponsors and pharmacies stated that when documentation was collected, attestations and certificates of completion were the most common types.

Although CMS does not specify whether sponsors must document their network pharmacies' completion of training to prevent fraud, waste, and abuse, it expects sponsors to be able to demonstrate this during an audit.<sup>32</sup> However, our followup interviews with sponsors suggested that they may not know of this requirement or may be unable to readily produce training documentation. Sponsors we interviewed told us that they delegate training functions to their PBMs, which are responsible for collecting and maintaining the documentation on the sponsors' behalf.

**Training materials generally reflected CMS guidance on content and source, with a few exceptions**

CMS guidance identifies five elements that sponsors should address to meet the training requirement on fraud, waste, and abuse: (1) fraud-related

statutes (e.g., False Claims Act, antikickback statute, HIPAA); (2) obligations of the pharmacy to have policies and procedures; (3) a process for reporting suspected fraud, waste, and abuse to sponsors; (4) protections against retaliation for employees who report; and (5) examples of fraud, waste, and abuse that can occur in pharmacies.<sup>33</sup> CMS also issued guidance in 2008 to clarify that pharmacies should not develop the training materials they use; rather, sponsors should administer training directly or provide materials to their network pharmacies so that pharmacy staff may administer the training to themselves.<sup>34</sup>

<sup>32</sup> 72 Fed. Reg. 68700, 68707 (Dec. 5, 2007).

<sup>33</sup> CMS Memorandum, *Fraud, Waste, and Abuse Training Clarification*, August 21, 2009.

<sup>34</sup> CMS Memorandum, *Fraud, Waste, and Abuse Training Requirements*, October 20, 2008.

## FINDINGS

### More than a third of the training materials failed to include information on HIPAA

Training materials submitted by sponsors and pharmacies included information on the False Claims Act and antikickback laws in nearly all cases. However, they did not consistently include information on HIPAA (see Table 2). HIPAA established privacy rules for handling patients' sensitive medical data. Pharmacy employees who are unfamiliar with that law could inadvertently reveal beneficiaries' medical data, placing them at risk for identity theft and other types of fraud.

Table 2: Fraud, Waste, and Abuse Statutes Included in Training Materials

Statute Element	Pharmacies (n=211)	Sponsors (n=209)
False Claims Act	96%	98%
Antikickback laws	94%	97%
HIPAA	55%	66%

Source: OIG survey of Part D network pharmacies, 2010.

### Most training materials included the other elements in CMS guidance

Training materials contained information on pharmacies' obligations to have policies and procedures on fraud, waste, and abuse; reporting processes; and retaliation protections for employees. Additionally, most materials from sponsors and pharmacies directed pharmacy employees to report fraud, waste, and abuse to their managers, to PBMs, or directly to sponsors (see Tables 3 and 4).

Table 3: Required Elements Included in Training Materials

Training Element	Pharmacies (n=211)	Sponsors (n=209)
Obligations to have policies and procedures	92%	82%
Process for reporting fraud, waste, and abuse	94%	86%
Protections for employees	92%	83%

Source: OIG survey of Part D network pharmacies, 2010.

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Table 4: Reporting Authorities Included in Training Materials

Reporting Authorities	Pharmacies (n=211)	Sponsors (n=209)
Pharmacy manager, PBM, or sponsor	69%	93%
OIG	52%	15%
CMS	8%	8%

Source: OIG survey of Part D network pharmacies, 2010.

Training materials also provided common examples of fraud, waste, and abuse that can occur in pharmacies. As Table 5 shows, such schemes include switching, splitting, or shorting prescriptions; billing for nonexistent prescriptions; and billing a sponsor for a brand-name drug but dispensing a generic. These are all examples that CMS recommended in guidance to sponsors regarding training material content.<sup>35</sup>

Table 5: Common Fraud Risks Described in Training Materials

Common Fraud Risk	Pharmacies (n=211)	Sponsors (n=209)
Switching, splitting, or shorting prescriptions	96%	89%
Billing for nonexistent prescriptions	94%	87%
Billing for brand-name but dispensing generic	91%	78%

Source: OIG survey of Part D network pharmacies, 2010.

**The sources for more than half of the training materials used by pharmacies were the pharmacies’ corporate offices, despite CMS guidance**

Despite CMS guidance to sponsors stating that pharmacies should not develop their own training materials, 51 percent of pharmacies used materials created by their corporate offices (see Table 6). However, 20 percent of pharmacies reported that they used materials that either a Part D sponsor or a sponsor’s PBM developed. Other sources included third-party vendors/consultants and professional associations.

<sup>35</sup> CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 9, § 70.1.3.

Table 6: Sources of Pharmacies’ Training Materials

Source	Pharmacies (n=335)
Pharmacy corporate office	51%
Third-party vendor or consultant	28%
Part D sponsor	14%
Professional association	6%
PBM	6%
Other	4%
Do not know	4%

Figures do not sum to 100% because some pharmacies indicated more than one source.

Source: OIG survey of Part D network pharmacies, 2010.

**Most sponsors could not determine the extent to which training was effective**

CMS requires sponsors to “provide effective training and education” for their network pharmacies.

CMS does not define what

constitutes “effective” training; rather, it instructs sponsors to provide training and education that are effective in detecting, preventing, and responding to fraud, waste, and abuse.

**Although 59 percent of sponsors reported that they assessed the training’s effectiveness, fewer than half used measures clearly linked to fraud, waste, and abuse**

Of the 153 sponsors that reported assessing the training’s effectiveness, 74 analyzed data that could demonstrate changes in pharmacy staffs’ understanding of fraud, waste, and abuse issues or changes in the reporting or detection of fraud, waste, and abuse. Two of these sponsors administered posttraining tests to pharmacy staff to determine their knowledge of fraud, waste, and abuse. The other 72 reviewed trends in fraud, waste, and abuse reporting; pharmacy audits; or analysis of pharmacy claims to determine the extent to which they were providing effective training.

The remaining 79 sponsors that reported determining the extent to which they provided effective training did not provide any metric that they used in assessing the effectiveness of training. Forty-eight of these sponsors reported determining that training was effective because it raised pharmacies’ awareness of fraud, waste, and abuse issues. The remaining sponsors in this group described their general oversight

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processes for pharmacies, their use of attestations, or feedback from pharmacies as the basis for assessing the training's effectiveness.

### **Forty-one percent of sponsors did not assess the effectiveness of their training**

Among 258 sponsors that responded to our survey, 105 did not determine the extent to which training was effective. Fifty-four of these 105 sponsors gave no explanation, and 37 said that the training was too new to assess because it was not required until 2009. The remaining sponsors said that they had no guidelines from CMS with which to assess it, that they were not required to assess it, or that they planned to begin assessing the training in the coming year. Although CMS did not enforce training for pharmacies until 2009, this training is not a new requirement in Part D. CMS has required sponsors to provide training for their employees since the start of the Part D program in 2006.



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

Fraud, waste, and abuse represent significant threats to Medicare Part D, making training on how to prevent them vital to safeguarding the program. Toward that end, CMS provided guidance on such training to strengthen network pharmacies' ability to prevent, detect, and respond to these threats. This study identified opportunities to help hone the effectiveness of that training.

Overall, we found that sponsors provided, and nearly all pharmacies took, training to prevent fraud, waste, and abuse in 2009. However, not all sponsors required documentation of training from their pharmacies.

Furthermore, although the content of the training generally reflected CMS guidance, more than a third of the training materials lacked information on HIPAA.

Even though CMS specifies that pharmacies should not develop training materials, we found that most of them were created by pharmacies.

Finally, our survey results and interviews also raise concerns about whether and how sponsors determine the extent to which their training and education are effective. Forty-one percent of sponsors did not assess the effectiveness of their training and education; of the 59 percent that did, fewer than half used measures clearly related to fraud, waste, and abuse.

Taken together, these results raise questions about the extent to which fraud, waste, and abuse training is effective in helping pharmacies prevent, detect, and respond to these threats.

Therefore, we recommend that CMS:

**Reiterate to sponsors their responsibilities to provide network pharmacies' training on Part D fraud, waste, and abuse**

To do so, CMS should reissue guidance to sponsors regarding its expectations for them to:

- develop and disseminate training materials to their network pharmacies;
- include HIPAA in their materials;
- maintain documentation that pharmacies have received training; and

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

- determine the extent to which they are providing effective training and education that reduce fraud, waste, and abuse risks.

### **Use its monitoring authority to determine compliance with training requirements**

CMS routinely audits sponsors' compliance plans to oversee their adherence to programmatic requirements. Toward that end, CMS should use these audits to ensure that sponsors are in compliance with all fraud, waste, and abuse training requirements noted above. To achieve this goal, CMS should:

- review training materials to ensure that pharmacies are not developing them;
- verify that all required contents, including HIPAA, are part of the materials;
- clarify its requirements regarding sponsors' obligations to collect documentation from their network pharmacies that they have taken training; and
- request documentation supporting the extent to which sponsors are developing and providing effective training and education for their network pharmacies.

### **Take steps to ensure that sponsors are providing effective training and education to prevent fraud, waste, and abuse**

CMS requires sponsors to provide their network pharmacies with training and education that are effective in preventing, detecting, and responding to fraud, waste, and abuse. To this end, CMS should:

- develop guidance for sponsors to use in assessing the effectiveness of training and education on fraud, waste, and abuse; or
- provide a forum (e.g., online or conference call) in which sponsors can share best practices used to determine the training's effectiveness. For example, sponsors could demonstrate the training's effectiveness using posttraining tests, analysis of pharmacy audits or claims data, or other quantifiable methods.

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

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

CMS concurred with our recommendations. The complete text of CMS's comments appears in Appendix B.

➤ A P P E N D I X ~ A

Table A-1: Confidence Intervals

Statistic	Sample Size	Point Estimate	95-Percent Confidence Interval
At least 87 percent of pharmacies reported that all of their staff received fraud, waste, and abuse training in 2009.	335	87.5%	82.9%–91.0%
Ninety-five percent of pharmacies reported that all of their registered pharmacists received fraud, waste, and abuse training in 2009.	335	95.0%	91.4%–97.2%
Eighty-eight percent of pharmacies reported that all of their pharmacy managers received fraud, waste, and abuse training in 2009.	335	88.3%	83.8%–91.7%
Ninety percent of pharmacies reported that all of their pharmacy technicians received fraud, waste, and abuse training in 2009.	335	90.3%	86.0%–93.3%
Fewer than 1 percent of pharmacies reported that most or some of their registered pharmacists received fraud, waste, and abuse training in 2009.	335	0.6%	0.1%–2.2%
Fewer than 1 percent of pharmacies reported that most or some of their pharmacy managers received fraud, waste, and abuse training in 2009.	335	0.3%	0.0%–1.8%
Two percent of pharmacies reported that most or some of their pharmacy technicians received fraud, waste, and abuse training in 2009.	335	1.7%	0.7%–4.1%
Eighty-four percent of pharmacies reported that their staff took training individually.	326	84.1%	80.0%–87.4%
Ten percent of pharmacies reported that their staff took a combination of group and individual training.	326	9.6%	7.0%–12.9%
Sixty-three percent of pharmacies reported that their training included a computer-assisted component.	326	62.6%	56.1%–68.7%
Thirty-one percent of pharmacies reported that their training included written materials.	326	31.3%	26.4%–36.7%

A P P E N D I X - A

Statistic	Sample Size	Point Estimate	95-Percent Confidence Interval
Twelve percent of pharmacies reported that their training included lecture and discussion.	326	11.6%	8.5%–15.5%
Thirty-five percent of pharmacies reported that sponsors had not asked them for documentation of training.	335	35.3%	29.3%–41.8%
Eighty-seven percent of pharmacies reported that attestations were the most commonly submitted type of documentation.	156	86.6%	79.3%–91.6%
Eighteen percent of pharmacies reported that certificates of completion were the most commonly submitted type of documentation.	156	17.7%	12.3%–24.9%
Ninety-six percent of training materials in 2009 contained information on the False Claims Act.	211	96.4%	91.4%–98.6%
Ninety-four percent of training materials in 2009 contained information on the antikickback statute.	211	94.3%	88.4%–97.3%
Fifty-five percent of training materials in 2009 contained information on the Health Insurance Portability and Accountability Act.	211	54.7%	46.2%–63.0%
Ninety-two percent of training materials submitted by pharmacies included obligations to have policies and procedures on fraud, waste, and abuse.	211	91.9%	85.8%–95.5%
Ninety-four percent of training materials submitted by pharmacies included a process for reporting fraud, waste, and abuse.	211	93.9%	88.7%–96.8%
Ninety-two percent of training materials submitted by pharmacies included protections for employees against retaliation.	211	91.8%	86.4%–95.2%
Sixty-nine percent of training materials from pharmacies directed pharmacy employees to report fraud, waste, and abuse to their managers, to Pharmacy Benefit Managers (PBM), or directly to sponsors.	211	69.3%	60.6%–76.8%
Fifty-two percent of training materials from pharmacies directed pharmacy employees to report fraud, waste, and abuse to the Office of Inspector General.	211	52.0%	43.6%–60.3%

A P P E N D I X - A

Statistic	Sample Size	Point Estimate	95-Percent Confidence Interval
Eight percent of training materials from pharmacies directed pharmacy employees to report fraud, waste, and abuse to the Centers for Medicare & Medicaid Services.	211	8.2%	4.9%–13.3%
Ninety-six percent of training materials from pharmacies list "switching, splitting, or shorting prescriptions" as a common fraud risk.	211	96.4%	91.4%–98.6%
Ninety-four percent of training materials from pharmacies list "billing for non-existent prescriptions" as a common fraud risk.	211	93.8%	88.3%–96.9%
Ninety-one percent of training materials from pharmacies list "billing for brand-name but dispensing generic" drugs as a common fraud risk.	211	91.3%	85.5%–94.9%
Fifty-one percent of pharmacies used materials created by their corporate offices.	335	50.5%	44.9%–56.1%
Twenty-eight percent of pharmacies used materials created by a third-party vendor or consultant.	335	27.7%	22.5%–33.6%
Fourteen percent of pharmacies used materials created by a Part D sponsor.	335	13.7%	10.4%–17.8%
Six percent of pharmacies used materials created by a professional association.	335	6.4%	4.0%–10.0%
Six percent of pharmacies used materials created by a PBM.	335	6.2%	3.9%–9.6%
Four percent of pharmacies said they used training materials from another source.	335	3.6%	2.0%–6.3%
Four percent of pharmacies do not know which organization created the training materials that they used.	335	3.6%	1.8%–7.0%

▶ A P P E N D I X ~ B

**Agency Comments**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

*Administrator*  
Washington, DC 20201

**DATE:** JUN 0 2 2011

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

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

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "Medicare Prescription Drug Sponsors' Training on Fraud, Waste, and Abuse" (OEI-01-10-00060)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General (OIG) draft report entitled, "Medicare Prescription Drug Sponsors' Training on Fraud, Waste, and Abuse." CMS provides guidance on fraud, waste, and abuse training to strengthen network pharmacies' ability to prevent, detect, and respond to threats.

The CMS appreciates OIG's efforts in working with us to help hone the effectiveness of that training. In accordance with our commitment to safeguard the Medicare trust fund, CMS will reissue guidance to sponsors reiterating their responsibilities to provide training on Part D fraud, waste, and abuse to their entities, determine sponsors' compliance with training requirements through routine audits, and will make available a Web-based Part C/D Training Fraud Module, as well as hard-copy training material, for sponsors to utilize. Lastly, CMS will work with sponsors to develop and share best practices in assessing the effectiveness of fraud, waste, and abuse training.

Our response to each of the OIG recommendations follows.

**OIG Recommendation**

The CMS should reiterate to sponsors their responsibilities to provide network pharmacies' training on Part D fraud, waste, and abuse.

**CMS Response**

The CMS concurs with this recommendation. CMS will reissue guidance to sponsors reiterating their responsibilities to provide training on Part D fraud, waste, and abuse to their first tier, downstream, and related entities.

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**OIG Recommendation**

The CMS should use its monitoring authority to determine compliance with fraud, waste, and abuse training requirements.

**CMS Response**

The CMS concurs with this recommendation. CMS will continue to determine sponsors' compliance with all fraud, waste, and abuse training requirements through the routine audits of the sponsors' compliance plans conducted during the fiscal year.

**OIG Recommendation**

The CMS should take steps to ensure that sponsors are providing effective training and education on fraud, waste, and abuse.

**CMS Response**

The CMS concurs with this recommendation and will take several steps to assist sponsors in their efforts to provide effective training on fraud, waste, and abuse. CMS will make available through its training Web site, MEDLearn, a Part C/D Training Fraud Module. For those participants interested in receiving Continuing Education Units (CEUs), a test will be included in the training module. For participants not interested in CEUs, a PowerPoint version of the same material will be made available. Additionally, CMS will work directly with plan sponsors to develop and share best practices in assessing the effectiveness of fraud, waste, and abuse training.

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



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

This report was prepared under the direction of Joyce Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston regional office, and Russell Hereford, Deputy Regional Inspector General.

Melissa Hafner served as the lead analyst for this study. Other principal Office of Evaluation and Inspections staff from the Boston regional office who contributed to the report include Tim Chettiath; central office staff who contributed include Robert Gibbons and Rita Wurm.

# *Office of Inspector General*

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