Office of Inspector General (OIG) Compliance Recommendations for Medicare Part D

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Conflict of Interest Statement

- My husband received a $100 honoraria to my from Qessential Medical Marketing last year

Objectives

- Describe the Medicare Part D Program fraud concerns
- Identify fraudulent practices targeted for OIG audits and investigations
- Discuss Health and Human Services (HHS) OIG recommendations to prevent fraud in the Medicare Part D Program
- Identify Medicare Part D Program controls for pharmacies
- Recognize the areas of increased scrutiny of Part D billings and the likelihood of additional drugs being added to the Part D Program’s utilization review program
What We Will Cover

- Medicare Part D Overview
  - Key compliance program requirements
- Part D Fraud
  - Types of fraud
  - Recent prosecutions
- Part D Program Integrity
  - Part D oversight
  - June 2015 OIG Portfolio: Ensuring the Integrity of Medicare Part D
  - June 2015 HHS OIG Data Brief: Questionable Billing and Geographic Hotspots
  - Practical takeaways
- 2016 OIG Work Plan - Part D
  - Importance of the OIG Work Plan
  - Certain areas in which the OIG perceives risk
  - Practical takeaways

Medicare Part D

- Voluntary Prescription Drug Benefit
- Established by the Medicare Prescription Drug, Improvement, Modernization Act (MMA) in 2003
  - Program began on January 1, 2006
- Private health insurers (Part D plan sponsors) contract with CMS to provide Part D benefits directly to beneficiaries

Medicare Part D

- Only way to access the benefit is through private insurance plans
  - No "government-run" Part D
- Beneficiaries receive benefits through stand-alone prescription drug plans or through Medicare Advantage prescription drug plans
  - Approximately 39 million beneficiaries
  - More than 2000 Part D plans
**Types of Plans**

**MA-PD Plans**
- MAOs must offer at least 1 MA plan that includes Part D benefits in each MAO service area
- Plan sponsor is also considered to be a Part D plan sponsor subject to Part D requirements
- ~14.1 million enrollees

**Stand-alone prescription drug plans (PDPs)**
- Only provide Part D benefits
- Add drug coverage to Original Medicare (Parts A and B)
- ~23.4 million enrollees

**Plan Payment**
- Annual bid process for Part D plan sponsors
- CMS pays plan sponsors a per member per month (PMPM) payment based on sponsor’s bid compared to benchmark
- The government shares some risk with plan sponsors in Part D (a distinction from Part C)
- Once an enrollee’s prescription drug spending reaches the out-of-pocket threshold (catastrophic cap), Medicare pays the majority of drug costs over the limit

**Covered Drugs**
- Definition of "Covered Drug":
  - Dispensed pursuant to a Rx and approved by FDA
  - Used for a medically accepted indication
  - Includes vaccines and insulin
- Exclusions:
  - Over the counter drugs (OTCs)
  - Weight loss medications
  - Drugs for cosmetic purposes
  - Fertility medications
  - Drugs for which coverage/payment is available under Medicare Parts A or B
Examples of FDRs

- Entities that provide services to MAOs or Part D Plan Sponsors downstream are First Tier, Downstream and Related Entities or "FDRs"
  - Includes our health provider clients (hospitals), pharmacy benefit managers, pharmacies

FDRs: Key Concepts

- Plan sponsor (MAO or PDP) maintains ultimate responsibility for fulfilling the terms of its contract with CMS
- But CMS requires plan sponsors to monitor and audit their FDRs to which they have delegated Part C or Part D functions to ensure FDRs are in compliance with applicable CMS laws
  - First tier entities must monitor the compliance of any downstream entity that performs Medicare-related functions

Key FDR Compliance Program Requirements

- Inclusion of required Medicare language in FDR contracts
  - Usually set forth in a Medicare Addendum
  - Include enrollee protection provisions, record retention requirements, compliance with sponsor’s contractual obligations with CMS
- Offshore Subcontractor Attestations
- Standards of Conduct
  - Distributed to FDRs by plan sponsor
Key FDR Compliance Program Requirements

- FWA and General Compliance Training
  - Required by FDRs upon 90 days of hire and annually thereafter
  - Part A/B providers and suppliers are deemed exempt from FWA training
  - January 1, 2016: Compliance Program training only applies to certain FDR staff; CMS temporarily suspending review of training certification in audit protocol to give FDRs/sponsors time to comply
- Reporting FWA and Compliance Concerns to Plan Sponsor
- Monitoring and Auditing of FDRs

Spending for Part D Drugs

From 2012 –2014, the OIG’s Part D investigations resulted in 339 criminal actions, 31 civil actions, and over $720 million in investigative receivables
- As of May 2015, OIG had 540 pending complaints and cases involving Part D
- Complaints and cases involving Part D increased over 130% in the last 5 years
- OIG noted that more than 1,400 pharmacies had questionable billing for Part D drugs
Focus on Part D Fraud

“OIG has made stopping Part D fraud a top priority.”
–Ann Maxwell, Assistant Inspector General

“A dangerous trend is fraudulent pharmacy billing for drugs...but exploitation of the Medicare prescription drug benefit will not be tolerated and suspects will face aggressive investigation and prosecution.”
–Shimon R. Richmond Special Agent in Charge, HHS-OIG Miami Regional Office

Types of Part D Fraud

- Drug diversion
- Prescription forging or altering
- Billing for drugs that are not dispensed
- Inappropriate dispensing
- Inducements, kickbacks and bribes
- Doctor shopping
- Pharmacy Shopping
- Identity theft

Recent Part D Prosecutions

United States v. Javaherian

- August 3, 2015. Los Angeles pharmacist sentenced to 18 months in prison for Medicare Part D fraud
  - Paid illegal cash kickbacks to Medicare beneficiaries to induce them to submit their prescriptions to his pharmacy
  - Filled some of the prescriptions, but also submitted false claims to Medicare Part D plan sponsors for prescriptions that he did not actually fill
  - Received approximately $644,060 in overpayments from Medicare
Recent Part D Prosecutions

United States v. Antonio Hevia et al.
- Charges: conspiracy to commit health care fraud and wire fraud; substantive counts of health care fraud; and conspiracy to defraud the US and pay and receive health care kickbacks
- Recruited individuals to be the owners of pharmacies in Miami-Dade County, which were used to submit false claims to the Part D program
- Instructed the staff at the pharmacies to submit false claims for prescription drugs that were not medically necessary and not provided to Part D beneficiaries
- Beneficiaries were frequently referred to the pharmacies by patient recruiters, who received kickbacks for referring patients
- Resulted in approximately $16.7 million in fraudulent payments

United States v. Kenia Gonzalez et al.

- Charges, including conspiracy to commit health care fraud, health care fraud and money laundering
- Submitted false claims via interstate wires to Medicare for prescription drugs that were not prescribed by physicians, not medically necessary and not provided to Medicare beneficiaries
- As a result, Part D plan sponsors, through their pharmacy benefit managers, made approximately $10,428,019 in payments
OIG Focuses on Part D

ENSURING THE INTEGRITY OF MEDICARE PART D

OIG Proactive Claims Analysis

- Identified potentially problematic billing patterns that raise concerns about the extent to which improper billing is going undetected.

OIG Proactive Claims Analysis

- OIG found that a number of retail pharmacies had questionable billing patterns:
  - Extremely high dollar amounts or numbers of prescriptions per beneficiary or per prescriber.
  - Could indicate that the drugs were not medically necessary or were never provided.
  - Questionable billing by > 700 physicians, most of whom ordered extremely high percentages of drugs with the potential for abuse.
Questionable Billing

- Questionable billing for Part D drugs based on five measures:
  1. Average number of prescriptions per beneficiary
  2. Percentage of prescriptions that were for commonly abused opioids
  3. Average number of prescribers for commonly abused opioids per beneficiary who received opioids
  4. Average number of types of drugs per beneficiary
  5. The percentage of beneficiaries with an excessive supply of a drug

<table>
<thead>
<tr>
<th>Measure</th>
<th>National Average</th>
<th>Median</th>
<th>Threshold for Extremely High Amounts</th>
<th>Number of Pharmacies That Billed Extremely High Amounts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average number of prescriptions per beneficiary</td>
<td>23</td>
<td>21</td>
<td>62</td>
<td>403</td>
</tr>
<tr>
<td>Percentage of prescriptions that were for commonly abused opioids</td>
<td>6%</td>
<td>6%</td>
<td>17%</td>
<td>499</td>
</tr>
<tr>
<td>Average number of prescribers for commonly abused opioids per beneficiary who received opioids</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>316</td>
</tr>
<tr>
<td>Average number of types of drugs per beneficiary</td>
<td>6</td>
<td>6</td>
<td>12</td>
<td>314</td>
</tr>
<tr>
<td>Percentage of beneficiaries with an excessive supply of a drug</td>
<td>0.5%</td>
<td>0.4%</td>
<td>1.9%</td>
<td>352</td>
</tr>
</tbody>
</table>

*The number of pharmacies with questionable billing practices for commonly abused opioids—does not equal the sum of this column, because some pharmacies billed extremely high amounts for more than one measure.


Pharmacy-Related Fraud

- Pharmacies with questionable billing practices raise concerns about pharmacy-related fraud schemes
- These schemes include:
  - Drug diversion
  - Billing for drugs that are not dispensed
  - Inappropriate dispensing
  - Kickbacks and bribes
Drug Diversion

- Growth in spending for commonly abused opioids, 2006-2014

>1,500 beneficiaries with questionable utilization patterns for HIV drugs
- No HIV diagnosis / indication of HIV treatment in their claims histories
- Received an excessive dose or supply of HIV drugs, and/or received HIV drugs from a high number of pharmacies or prescribers

Geographic Hotspots

**OIG Focuses on Part D**

ENSHURING THE INTEGRITY OF MEDICARE, PART D

**Part D Oversight**

**Responsible Parties**

- CMS
- Plan Sponsors
- Medicare Drug Integrity Contractor (MEDIC)
- OIG

**OIG-Identified Shortcomings**

1. the need to more effectively collect and analyze program data to proactively identify and resolve program vulnerabilities and prevent fraud, waste, and abuse before it occurs
2. the need to more fully implement robust oversight designed to ensure proper payments, prevent fraud, and protect beneficiaries
Part D Oversight

CMS Responsibilities

- Overseeing the Part D program
- Overseeing the plan sponsors and MEDIC
  - Defining their requirements for carrying out program integrity functions
  - Monitoring their performance

Plan Sponsors Responsibilities

- Paying claims, monitoring billing patterns, and establishing compliance plans that specify their procedures for preventing and detecting fraud, waste, and abuse
- Ensuring that pharmacies meet regulatory and compliance requirements

MEDIC Responsibilities

- Identifying and investigating potential fraud and abuse, referring cases to law enforcement, and fulfilling requests for information from law enforcement
- Investigating potential fraud and abuse referred to it through external sources, such as complaints
- Identifying potential fraud and abuse through proactive methods, such as data analysis
Part D Oversight

OIG Responsibilities
- Investigating Part D fraud and abuse
- Issuing legal guidance regarding Part D compliance
- Auditing and identification of systemic Part D program vulnerabilities
- Prosecuting of individuals accused of defrauding Part D

CMS Shortcomings
- CMS does not require plan sponsors to report information on fraud, and most have chosen not to voluntarily report this information
- 28% percent of stand-alone plan sponsors did not identify any potential fraud and abuse
- 34% of Medicare Advantage plans did not identify any potential Part D fraud and abuse

Plan Sponsor Shortcomings
- Most potential incidents of fraud and abuse were associated with only a small number of plan sponsors
- Low level of fraud identified by some plan sponsors raises questions about the sufficiency of their fraud and abuse detection programs
- Not all plan sponsors conducted inquiries, initiated corrective actions, or made referrals for further investigation
MEDIC Shortcomings

- The MEDIC does not capitalize on proactive data analysis to detect fraud, waste, and abuse
- Relied on external sources (e.g., beneficiary complaints) to identify potential fraud and abuse

Part D Oversight Structure

CMS and plan sponsor oversight is not sufficient to protect part D

Invalid Prescriber Identifiers

- Plan sponsors and CMS did not institute adequate procedures or oversight to identify claims with invalid prescriber identifiers
  - Part D paid $1.2 billion for claims with invalid prescriber identifiers in 2007
  - Approximately $20.6 million was paid in 2007 for Schedule II drug claims with invalid prescribers
Lack of Authority to Prescribe

- Part D inappropriately paid for drugs ordered by individuals without prescribing authority (e.g., massage therapists and athletic trainers)
- Tens of thousands of drugs ordered by individuals without prescribing authority were controlled substances

Schedule II Drug Refills

- Plan sponsors frequently lack adequate controls to prevent Schedule II drug refills
- Allowing Schedule II refills may result in the diversion of controlled substances or drug misuse
- In 2009, Part D inappropriately paid $25 million for Schedule II drugs billed as refills

Deceased Beneficiaries

- CMS had insufficient safeguards to prevent payments after beneficiaries’ deaths
- Between 2006 and 2007, CMS paid approximately $3.6 million on behalf of deceased beneficiaries
- After implementing an automated process to prevent these payments, CMS still allowed Part D payments on behalf of 5,101 deceased beneficiaries in 2011
Future Expectations: Increased Oversight

- Increased proactive risk analysis by CMS and MEDIC:
  - New Pharmacy Risk Assessment tool for plan sponsors to conduct additional analysis
  - MEDIC given access to Claims data from Medicare Parts A and B
  - MEDIC has increased the percentage of proactive investigations
  - OIG calls for CMS to proactively analyze claims data to identify beneficiaries with aberrant use and restrict them to certain prescribers and pharmacies

Increased Oversight

Oversight Tools

- MEDIC has new regulatory authority to request and collect information directly from pharmacies to investigate potential fraud and abuse. See 42 CFR § 423.505(i)(2)(ii)

Invalid Prescribers

- CMS now requires plan sponsors to identify invalid prescriber identifiers and to verify that prescribers have the requisite authority to prescribers
- Increased CMS monitoring of prescribers through MEDIC
- MACRA requires OIG to evaluate the above controls for effectiveness
Increased Oversight

Excluded Providers
- CMS providing data to plan sponsors to help in identification of claims from excluded providers
- CMS contractor audits of excluded providers

Schedule II Drugs
- Stronger controls implemented by plan sponsors
- CMS contractor audits of refills of controlled substances in the Part D program
- OIG calls for CMS to exclude Schedule II refills when calculating year end payments to plan sponsors

Deceased Beneficiaries
- MACRA requires CMS to establish procedures to ensure that claims are not paid on deceased beneficiaries
- OIG to evaluate CMS’s procedures
How Should Pharmacies Respond?

- Periodically review your compliance program
- Update it as appropriate to ensure that you have controls in place to comply with applicable laws and regulations
- Have controls in place
- Include a self-audit
- Be aware that some criminals obtain prescription drugs on behalf of deceased beneficiaries and watch for suspicious activity

How Should Pharmacies Respond?

- Have controls in place to:
  - Ensure that only claims are submitted for medications prescribed by an individual who has prescriptive authority
  - Ensure that only Program claims are submitted that reflect valid prescriber identifiers
  - Reduce the risk of submitting claims for prescriptions issued by excluded prescribers
  - Avoid refilling Schedule II prescriptions and submitting claims for such refills

In the Future

- Greater scrutiny of Program billings, particularly by Sponsors
- Additional drugs to be added to the Program's utilization review program
- The potential that, in the future, certain beneficiaries could be limited to use a set number of pharmacies and/or prescribers
OIG 2016 Work Plan

- OIG 2016 Work Plan identifies Medicare Part D pharmacy enrollment, drug reimbursement and durable medical equipment as new fraud and abuse focus areas.

OIG Work Plan: What is it?

- The OIG publishes an annual document called the Work Plan that describes new and ongoing programs and activities that the OIG has identified as critical to its mission.
- About 80 percent of the OIG’s resources are allocated to work related to CMS.
- Over half the Plan is devoted to Medicare, Medicaid, and other CMS-related projects.

OIG Work Plan: What is it?

- The Plan is developed taking into consideration:
  - OIG legal authority, Congressional and HHS requests
  - Significant challenges facing the HHS
  - GAO and OMB issues
  - Action to implement prior recommendations
- Serves as a useful tool for Medicare providers in identifying and prioritizing compliance risk areas each year.
- Benefit: will assist in fine tuning CMS billing requirements to ensure both maximum reimbursement and errors.
Work Plan Subject Areas

- With a focus on Medicare and Medicaid, subject areas include:
  - Hospitals
  - Home Health
  - Nursing Homes
  - Hospice Care
  - Physicians
  - Medical Equipment and Supplies
  - Part B Drug Reimbursement
  - Mental Health Services
  - And many others

OIG Work Plan

New Topics for 2016

- Medicare Part D Beneficiaries’ Exposure to Inappropriate Drug Pairs
- Medicare Part D Eligibility Verification Transactions
- Part D Pharmacy Enrollment
- Increase in Prices for Brand Name Drugs Under Part D

2016 OIG Work Plan

- Medicare Part D Beneficiaries’ Exposure to Inappropriate Drug Pairs
  - OIG plans to review prescriptions of drugs that should not be combined with other drugs, including those that have a severe interaction when combined and those that should not be co-prescribed with component drugs
2016 OIG Work Plan

Medicare Part D Eligibility Verification Transactions

OIG will review Medicare Eligibility Verification transactions, also known as E1 transactions, submitted by pharmacies to a true out-of-pocket ("TrOOP") facilitator to determine a beneficiary's Part D eligibility and insurance coverage information. OIG plans to review these transactions to assess the validity of the data.

Part D Pharmacy Enrollment

OIG plans to review CMS's Part D pharmacy oversight ability. Additionally, OIG plans to determine the number of the pharmacies that bill for high risk drugs and are enrolled in Medicare. Previous OIG reports have raised concerns about Part D fraud and oversight. In June 2015, OIG was involved in the largest health care fraud takedown in history that mostly concerned prescription drugs and pharmacies.

Increase in Prices for Brand Name Drugs Under Part D

OIG plans to evaluate pharmacy reimbursement for Part D brand name drugs that have changed in price from 2010 to 2014 against the rate of inflation, as many brand name drug prices have risen substantially more than the inflation rate since 2002.
2016 OIG Work Plan

OIG will continue to audit in 2016

- Risk-sharing payments between Medicare and Part D plan sponsors
  - If the existing risk thresholds remained at 2006/2007 levels, cost savings could have been realized
- Financial interests reported to CMS under the Open Payments Program
  - Extent to which CMS oversees manufacturers and group purchasing organizations' data reporting compliance pursuant to § 6002 of the Affordable Care Act

- Part D sponsors' compliance with Medicare requirements for reporting direct and indirect remunerations (i.e., rebates, subsidies and other price concessions) from sources serving to reduce Part D sponsors' costs for drugs
- Dual-eligible beneficiaries' access to commonly used Part D drugs
- CMS’s steps taken to improve oversight of Part D sponsors' Pharmacy and Therapeutics committee conflict of interest procedures

- Retail pharmacies, previously identified as having questionable Part D billing, and whether they adequately submitted Medicare Part D records in compliance with applicable requirements
- Quality of Sponsor data used in calculating Medicare Part D coverage gap discounts
2016 OIG Work Plan

Prescription Drugs

- Part B Payments for Drugs Purchased Under the 340B Program. OIG plans to consider the financial impact of shared savings arrangements on 340B covered entities, the Medicare program and Medicaid beneficiaries. Specifically, OIG anticipates reviewing ways that would allow Medicare recipients to participate in the 340B program.

2016 OIG Work Plan

Prescription Drugs (cont.)

- Covered Uses for Medicare Part B Drugs. OIG plans to review CMS’s and its claims processing contractors’ oversight actions for Part B drug payments and the challenges those contractors face. OIG is concerned with a lack of oversight mechanisms that could lead to payment for uses that are not medically accepted, commonly referred to off-label use.

2016 OIG Work Plan

The following topics are repeated in the 2016 Plan, indicating that OIG will continue to audit and review these areas:

- Comparison of average sales price to average manufacturer prices for Medicare Part B drugs
- Payments for immunosuppressive drug claims with KX modifiers
Practical Takeaways

- The OIG Work Plan is a valuable resource that providers can use to enhance their compliance programs annually.
- Be certain that you understand the issue as stated by the OIG and think in broader terms.
- Pharmacies and Sponsors should be conducting annual audits.

Summary

- Enormous Challenges for Healthcare Compliance
- The Department of Justice, along with its law enforcement partners, is committed to aggressive investigation and prosecution of Part D fraud.

Summary

- Part D sponsors, PBMs, and pharmacies should:
  - Closely monitor any OIG actions relating to Part D.
  - Expect to see additional oversight by CMS and increased requests for information and data.
  - Implement robust policies and procedures designed to identify and stop potential Part D fraud and abuse.
  - Pharmacies should implement controls and auditing practices.
  - Pharmacies should carefully review their practices and billings to ensure that they are not engaging in questionable billing of Part D drugs as identified by the OIG.
Please visit the Hall Render Blog at http://blogs.hallrender.com for more information on topics related to health care law.

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