



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**

# OIG Work Involving Prescription Drug Pricing and Payments

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## Overview

- **OIG Mission and Structure**
- **Recently Completed and Ongoing Evaluations Involving Medicaid Drug Rebates and Payments**
- **Recently Completed and Ongoing Evaluations Involving Part B and Part D Drug Payments**
- **OIG Work Plan and Future OIG Evaluations**





## OIG Mission and Structure

- OIG's mission, as mandated by Public Law 95-452 (as amended), is to protect the integrity of Department of Health and Human Services (HHS) programs, as well as the health and welfare of the beneficiaries of those programs





## OIG Mission and Structure

- OIG has a responsibility to report to the Secretary and to Congress whenever we find program and management problems
- OIG's duties are carried out through a nationwide network of audits, investigations, evaluations, and other mission-related functions





## OIG Mission and Structure

- For FY 2011, OIG-reported savings and expected recoveries totaled \$25 billion
  - Excluded 2,662 individuals or entities from participation in Federal healthcare programs
  - Completed 723 criminal and 382 civil actions





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## OIG Mission and Structure

### OIG Components

- Office of Audit Services
- Office of Counsel to the IG
- Office of Investigations
- Office of Evaluation and Inspections





## OIG Mission and Structure

### Office of Audit Services

- Provides auditing services for HHS
- Examines the performance of HHS programs and/or its grantees and contractors
- Helps reduce waste, abuse, and mismanagement of programs
- Promotes economy and efficiency throughout HHS





## OIG Mission and Structure

### Office of Counsel to the Inspector General

- Provides general legal services to OIG
- Represents OIG in all civil and administrative fraud and abuse cases involving HHS programs
- Negotiates and monitors corporate integrity agreements
- Issues advisory opinions, fraud alerts, and guidance to health care providers and others on the application of fraud and abuse statutes







## OIG Mission and Structure

### Office of Investigations

- Conducts criminal, civil, and administrative investigations of fraud and misconduct
- Actively coordinates with the Department of Justice and other law enforcement entities
- Efforts often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties





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## OIG Mission and Structure

### Office of Evaluation and Inspections (OEI)

- Conducts national evaluations to provide timely, useful, and reliable information
- Focuses on fraud, waste, and abuse prevention
- Promotes economy, efficiency, and effectiveness
- Presents practical recommendations for improving programs





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# Recently Completed and Ongoing Evaluations Involving Medicaid Drug Rebates and Payments

## States' Collection of Rebates for Medicaid MCO Utilization

October 2012





## Recent Evaluation Involving Medicaid Rebates

### ACA Expansion of the Rebate Requirement

- Medicaid Managed Care Organizations (MCO) are required to report drug utilization data to States
- States are required to collect rebates from manufacturers for drugs paid through MCOs





## Recent Evaluation Involving Medicaid Rebates

In October 2011, OEI sent surveys to States Medicaid agencies.

These surveys asked about the:

- State's contracts with MCOs and methods used to pay for drugs in MCOs (e.g., carve-in or carve-out approach)
- Quality and timeliness of the MCOs' drug utilization data
- Procedures used to invoice manufacturers for MCO rebates
- Dollar amount of MCO rebates collected from manufacturers





## Recent Evaluation Involving Medicaid Rebates

### States' MCO Drug Coverage Approach From March 23, 2010 to October 1, 2011

Payment Approach	Number of States
Only Maintained a Carve-In Approach	16
Changed from a Carve-Out to a Carve-In Approach	3
Combination of Carve-In and Carve-Out Approach	6
<b>Total Number of States that Paid for Drugs Through MCOs</b>	<b>25</b>





## Recent Evaluation Involving Medicaid Rebates

### States' MCO Drug Coverage Approach From March 23, 2010 to October 1, 2011

Payment Approach	Number of States
Only Maintained a Carve-Out Approach	10
Did Not Have MCO Contracts	15
<b>Total Number of States that Did Not Pay for Drugs Through MCOs</b>	<b>25</b>





## Recent Evaluation Involving Medicaid Rebates

### Data Provided to States by MCOs

- Most carve-in States received all the data necessary for rebate invoicing from their MCOs
- Data was generally provided within 60 days after a quarter
- States performed at least one type of verification check on the MCOs' data







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## Recent Evaluation Involving Medicaid Rebates

12 of 22 carve-in States collected \$1.6 billion in MCO rebates for the second quarter of 2010 through the second quarter of 2011





## Recent Evaluation Involving Medicaid Rebates

The 12 carve-in States invoiced manufacturers for these rebates by sending:

Invoice Method	Number of States
One Invoice for All MCO Utilization and a Separate Invoice for FFS Utilization	10
Individual Invoices for Each MCO and a Separate Invoice for FFS Utilization	1
One Invoice That Combines MCO and FFS Utilization	1





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## Recent Evaluation Involving Medicaid Rebates

10 of 22 carve-in States had not invoiced manufacturers and collected MCO rebates at the time of our survey





## Recent Evaluation Involving Medicaid Rebates

The 10 States that had not invoiced intend to:

- Begin invoicing manufacturers by the end of 2012
- Retroactively invoice dating back to ACA's enactment (March 2010)
- Send one invoice for MCO utilization and a separate invoice for FFS (only in 7 States)





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## Recent Evaluation Involving Medicaid Rebates

Five of the 25 States that did not pay for drugs through MCOs changed the structure of their drugs programs as a result of the rebate expansion





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## Recent Evaluation Involving Medicaid Rebates

We recommended that CMS follow up with the 10 States that had not collected rebates for drugs dispensed to Medicaid MCO beneficiaries, and to take action to enforce rebate collection (if necessary)





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## Recent Evaluation Involving Medicaid Rebates

Recently Completed and Ongoing  
Evaluations Involving Medicaid Drug  
Rebates and Payments

Analyzing Changes to Medicaid Federal  
Upper Limit Amounts





## Recent Evaluation Involving Medicaid Rebates

- Prior OIG work found that Federal Upper Limits often greatly exceeded prices available in the marketplace
- Provisions in the Deficit Reduction Act of 2005 would have changed the methodology used to calculate FUL and most likely would have resulted in lower FUL amounts
- Due to an injunction, CMS could not implement these provisions







## Recent Evaluation Involving Medicaid Rebates

- ACA also included provisions to change FUL amounts
  - 175% of the weighted average AMP
- CMS released new FULs in draft form in September 2011





## Recent Evaluation Involving Medicaid Rebates

We compared:

- FUL amounts based on published prices to FUL amounts based on post-ACA AMPs
- Both FUL amounts to pharmacy acquisition cost





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## Recent Evaluation Involving Medicaid Rebates

FUL amounts based on published prices were more than four times greater than sampled pharmacy acquisition costs, in the aggregate





## Recent Evaluation Involving Medicaid Rebates

FUL amounts based on AMPs:

- Were 61 percent lower than FUL amounts based on published prices, at the median
- Still exceeded pharmacy acquisition costs in the aggregate





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## Recent Evaluation Involving Medicaid Rebates

We recommended that CMS complete implementation of the AMP-based FUL amounts





## Ongoing Evaluations Involving Medicaid Drugs

- Zero-dollar URAs
- State Experiences with Rebate Disputes
- State Maximum Allowable Cost Programs
- Supplemental Medicaid Rebates





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# Recently Completed and Ongoing Evaluations Involving Part B and Part D Drug Payments

October 2012





## Recent Evaluations Involving Medicare Drugs

- Medicare Payments for Drugs Used to Treat Wet Age-Related Macular Degeneration
- Quarterly ASP-AMP Comparisons
- Retail Pharmacies with Questionable Part D Billing







## Ongoing Evaluations Involving Medicare Drugs

- Least Costly Alternative Policies for Certain Prostate Cancer Drugs
- Payments for DME Infusion Drugs
- Potential Rebates Under Medicare Part B
- Annual Fee on Brand Drug Manufacturers
- Part D Payments for Drugs Included in Discount Generic Programs
- Manufacturer Copay Coupons





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# Future OEI Evaluations Involving Prescription Drug Pricing and Payments

October 2012





## Future Evaluations

### The OIG Work Plan

- Mandatory OIG reviews
- Requests from Congress and HHS management
- HHS management and performance challenges
- Discussions with CMS and other HHS agencies
- Emerging issues
- Unimplemented OIG recommendations





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## Future Evaluations Involving Medicaid Drugs

- Update on Manufacturer AMP Reporting
- Authorized Generics
- Retail Pharmacies' Discount Generic Drug Programs





## Future Evaluations Involving Medicare Drugs

- Off-Label Use of Medicare Part B Drugs
- ASP Fluctuation
- Price Increases in Part D
- Update on Medicare Payments for ESRD Drugs





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- OIG Work Plan and all reports available at [www.oig.hhs.gov](http://www.oig.hhs.gov)
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