Effective Strategies for Addressing Overutilization and Abuse of Prescription Drugs in Medicare Part D

CMS' Drug Utilization Review Requirements and Initiatives

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Overview

- Background
- Formulary Review Process
- Improving Drug Utilization Review Controls in Part D
- Formulary Management Strategies
- Opioid Overutilization Policy Development
- The Overutilization Monitoring System
- Impact of CMS Policy
- Compliance Outreach

Background

- As described in section 1860D-11(i)(2) of the Act, CMS cannot mandate a national formulary. However, CMS has exercised its antidiscrimination authority under section 1860D-11(e)(2)(D)(i) to ensure that Part D plan formularies do not substantially discourage enrollment by certain Part D eligible individuals
- Part D formulary submissions must be reviewed and approved prior to bid approval

Part D Formulary Review Process

- CMS Formulary Reference File (FRF)
  - The FRF includes RXCUIs, adopted from NLM's RxNorm system, to represent distinct brand names, generic names, strengths, routes of administration, and dosage forms of drugs
  - The FRF serves as a pick-list of drugs for formulary inclusion that streamlines the submission and review process, and results in improved synchronization of CMS and plan sponsor files
  - Not a "coverage" list for Part D drugs

Part D Formulary Review Process (continued)

- Formularies are submitted and reviewed via the Health Plan Management System (HPMS)
- Submissions are based on the FRF
- One formulary (FID) can be used across multiple plans
- The drug list, associated utilization management requirements, and tiering are reviewed in 3 stages
- During each review stage, Part D sponsors can provide clinical justifications, revised submissions, or both
- The final stage of the review involves addressing any unresolved issues, formulary negotiations, and conditional approvals

Improving Drug Utilization Review Controls in Part D – Level One

- Level One: Improved Use of Concurrent Claim Edits (Safety Controls at Point of Sale
  - Early Refill Edits
  - Therapeutic Duplication Edits
  - Age/Gender Edits
  - Quantity Limits At or Above FDA Max Dose

Reference: CY 2013 Final Call Letter

Improving Drug Utilization Review Controls in Part D – Level Two

- Level Two: Improved Use of Formulary Management Designs
  - Quantity Limits where no clear FDA Max Dose
  - Quantity Limits Below FDA Max Dose
  - Prior Authorization Criteria
  - Step Therapy Criteria

Reference: CY 2013 Final Call Letter

Improving Drug Utilization Review Controls in Part D – Level Three

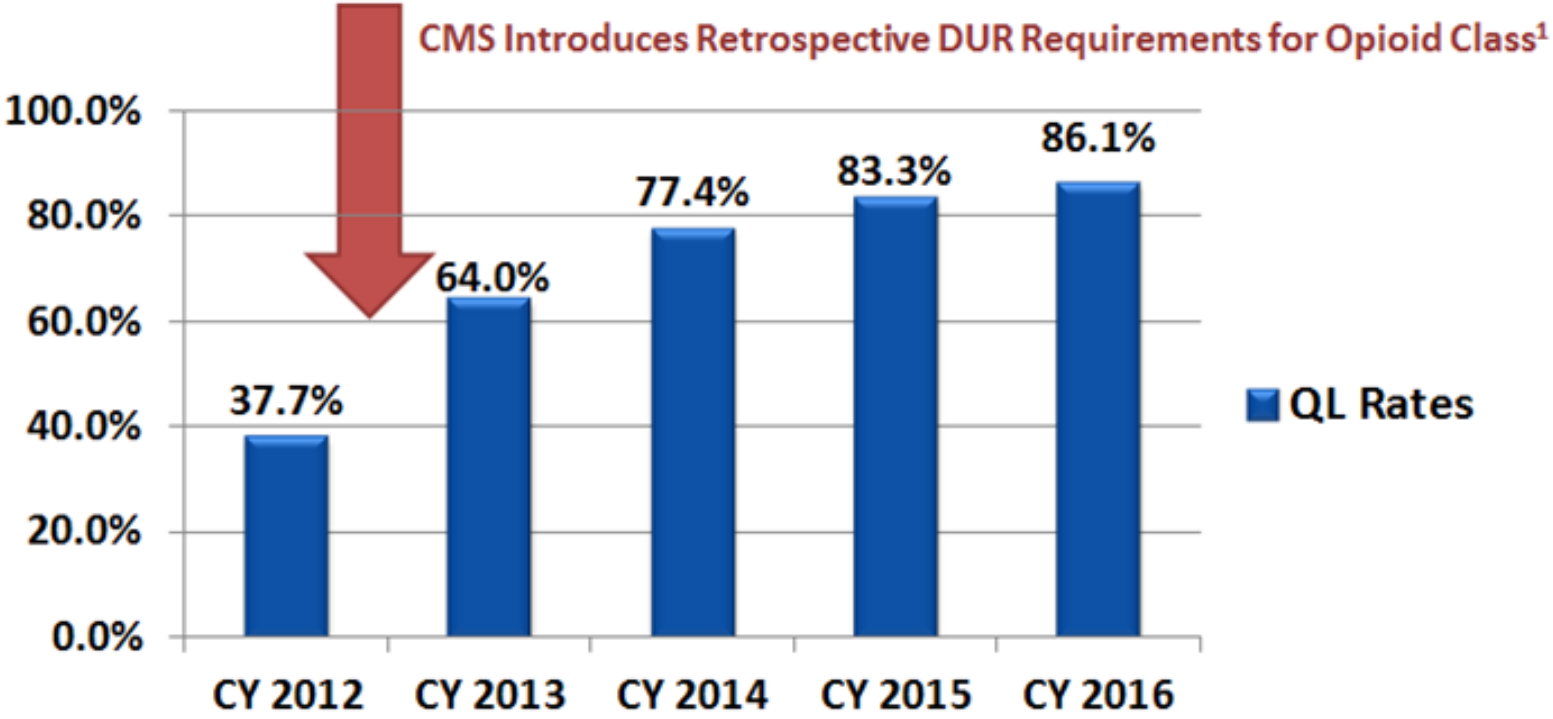
- Level Three: Improved Retrospective DUR Programming & Case Management
  - Retrospective review of claims data to identify egregious patterns of inappropriate use of specific drugs or groups of drugs among Part D enrollees
  - DUR programming and case management to detect and prevent inappropriate overutilization should events go undetected despite claim level controls

Reference: CY 2013 Final Call Letter

Formulary Management Strategies in Practice

- Quantity Limits
- Prior Authorization
- Step Therapy

QL Rates for Opioid Class, CY 2012 – CY 2016



Source: CY12-16 HPMS approved formulary data

1. CY 2013 Final Call Letter

QL Rate Changes

Brand Name	Generic Name	Dose Form	% with QL 2012	% with QL 2016	Absolute Difference
ROXICET	OXYCODONE HCL/ACETAMINOPHEN	ORAL SOLUTION	15.8%	92.9%	77.1%
ROXICODONE	OXYCODONE HYDROCHLORIDE	ORAL TABLET	10.5%	86.8%	76.3%
ROXICODONE	OXYCODONE HCL	ORAL TABLET	11.8%	85.5%	73.7%
	OXYCODONE HCL	ORAL TABLET	13.9%	87.4%	73.5%
	OXYCODONE HCL	ORAL CAPSULE	10.0%	83.2%	73.2%
	MORPHINE SULFATE	ORAL TABLET	12.0%	84.7%	72.7%
	HYDROMORPHONE HCL	ORAL TABLET	13.3%	85.6%	72.3%
DILAUDID	HYDROMORPHONE HCL	ORAL TABLET	10.0%	81.6%	71.6%
	LEVORPHANOL TARTRATE	ORAL TABLET	8.2%	79.8%	71.6%
	CODEINE SULFATE	ORAL TABLET	8.9%	79.4%	70.5%

Source: CY12-16 HPMS approved formulary data

Cumulative Morphine Equivalent Dose (MED) POS Edit

- In the CY 2014 Call Letter, CMS strongly encouraged sponsors to develop the ability to implement plan-level POS edits based upon cumulative MED across the opioid class
- The CY 2016 Call Letter continued to urge sponsors to implement a soft edit and build the capacity for a more sophisticated POS edit

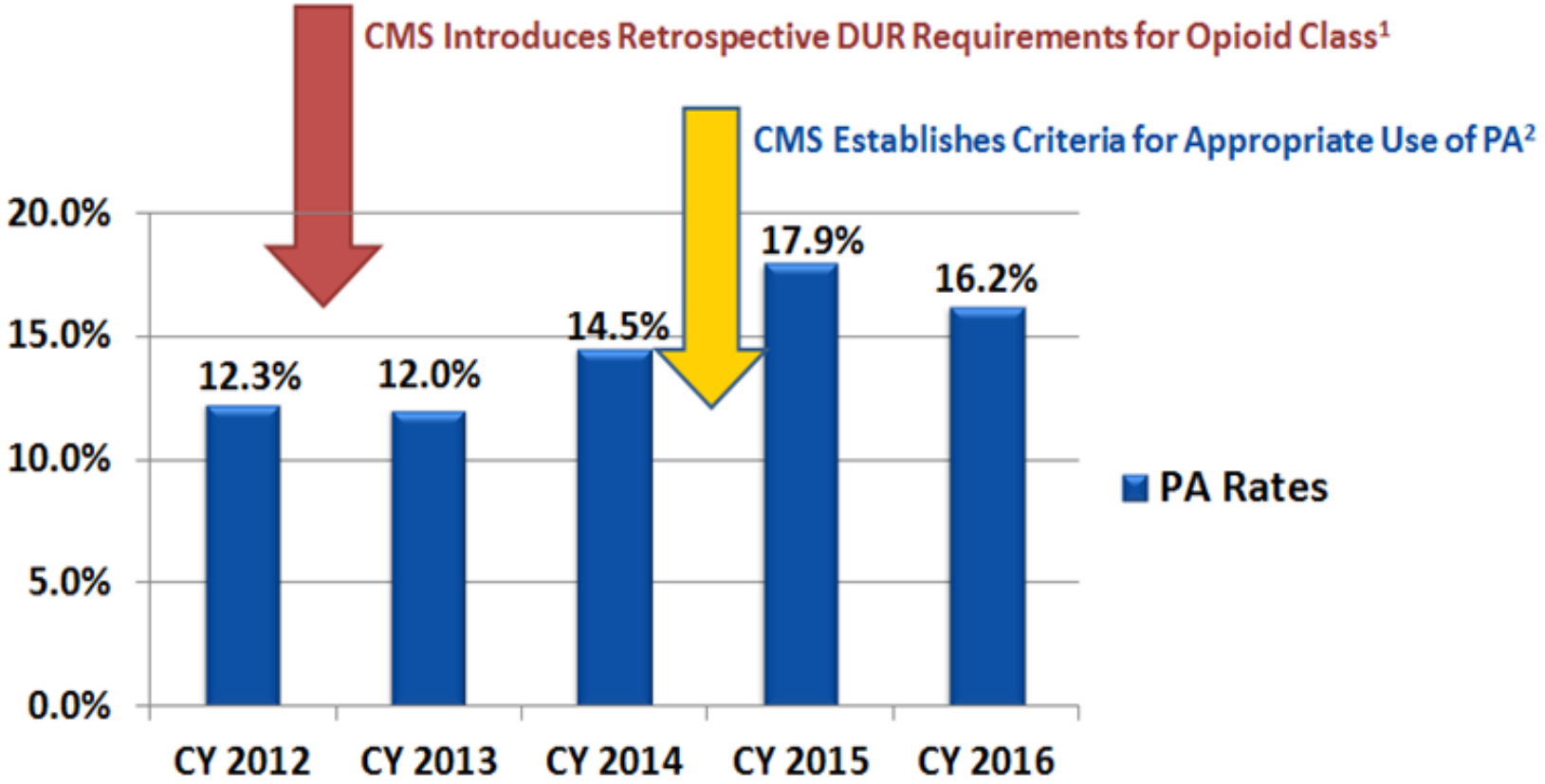
Cumulative MED POS Edit Requirements

- Submit the lesser of either the plan-approved QL for the individual opioids or the QL that is equivalent to the cumulative MED level to be applied across the opioid class
- Submit details to Part D mailbox
  - MED level
  - Written description of the program (e.g., days in excess of accumulated level that triggers edit)
  - Mechanism to resolve the edits

Cumulative MED POS edit CY 2014 – CY 2016

Year	# of Cumulative MED POS Edits	# of FIDs	% of FIDs with a Cumulative POS Edit
2014	0	437	0%
2015	36	467	7.7%
2016	108	456	23.7%

PA Rates for Opioid Class, CY 2012 – CY 2016



Source: CY12-16 HPMS approved formulary data

1. CY 2013 Final Call Letter

2. CY 2015 Final Call Letter

Appropriate Use of PA to Determine Part D Drug Status

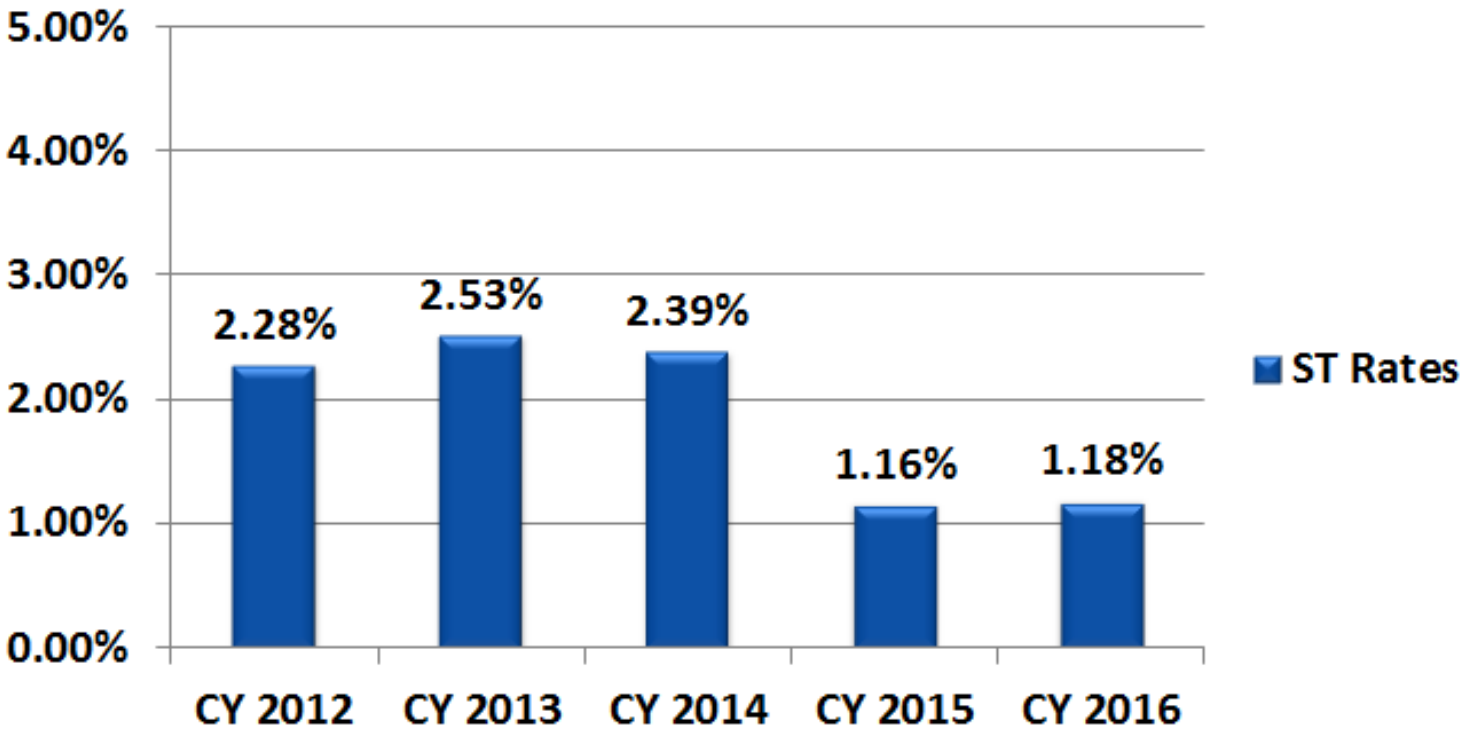
- As outlined in the CY 2015 Call Letter, CMS established criteria for scenarios where plan sponsors are expected to implement POS edits for PA on drugs that have the highest risk of non-Part D covered uses:
  - High likelihood of coverage under Parts A or B
  - High likelihood that the drug is Part D excluded as defined in section 1927(d)(2) of the Act
  - High likelihood of use for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act
- Examples include Transmucosal Immediate Release Fentanyl (TIRF) drugs and Cialis (tadalafil)

PA Rate Changes

Brand Name	Generic Name	Dose Form	% with PA 2012	% with PA 2016	Absolute Difference
	CODEINE/CARISOPRODOL/ASPIRIN	ORAL TABLET	26.8%	100%	73.2%
	ACETAMINOPHEN / BUTALBITAL / C	ORAL CAPSULE	0.0%	69.9%	69.9%
	PENTAZOCINE HCL/NALOXONE HCL	ORAL TABLET	9.8%	63.0%	53.2%
	MEPERIDINE HYDROCHLORIDE	ORAL TABLET	17.4%	59.7%	42.3%
	MEPERIDINE HCL	ORAL TABLET	17.4%	59.5%	42.1%
SUBSYS	FENTANYL	MUCOSAL SPRAY	65.3%	100%	34.7%
	MEPERIDINE HCL	ORAL SOLUTION	18.5%	51.5%	33.0%
DEMEROL	MEPERIDINE HYDROCHLORIDE	ORAL TABLET	28.6%	55.6%	27.0%
LAZANDA	FENTANYL CITRATE	NASAL SPRAY	79.0%	100%	21.0%
ABSTRAL	FENTANYL CITRATE	SUBLINGUAL TABLET	79.3%	100.%	20.7%

Source: CY12-16 HPMS approved formulary data

ST Rates for Opioid Class, CY 2012 – CY 2016



Source: CY12-16 HPMS approved formulary data

Overutilization Policy Development

- Effective January 1, 2013, CMS implemented new policy in Medicare Part D requiring sponsors to better address potential overutilization of opioids in their prescription drug benefit plans through improved drug utilization controls and case management
- Comprehensive policy was set forth in the final Call Letter (April 2, 2012) for CY 2013 and in more detail in final supplemental guidance (September 6, 2012)

Overutilization Policy Development, 2014 Call Letter

- CMS strongly encourages all sponsors to develop the ability to implement plan-level POS edits based upon cumulative morphine equivalent dose (MED) across the opioid class as soon as possible
- Sponsors may voluntarily expand the Part D Policy on Improving Utilization Review Controls to other drugs or classes of drugs, which would include notifying CMS and the affected beneficiaries of any beneficiary-level claim edits that will be implemented

Overutilization Policy Development, 2015 Call Letter

- CMS expects Part D sponsors to implement soft formulary-level safety edits at POS at a minimum to further reduce cumulative acetaminophen (APAP) overutilization among their enrollees
- Part D sponsors should lower their internal opioid criteria for retrospective identification of opioid overutilization and subsequent case management to be no less restrictive than 120 mg MED daily dose over at least 90 consecutive days as used by CMS

Overutilization Policy Development, 2016 Call Letter

- CMS encouraged sponsors to implement a soft, formulary-level cumulative MED POS edit and prepare for a more sophisticated POS edit in 2017
- New opioid and APAP Daily Dose rates will be added to the Overutilization Monitoring System for informational purposes only
- CMS will investigate the concurrent use of buprenorphine and opioids in Part D

Overutilization Monitoring System (OMS)

- The OMS was implemented in July 2013 to oversee sponsors' compliance with CMS' new opioid overutilization policy
- Part D sponsors are provided quarterly reports on high risk beneficiaries, and submit the outcome of their review of each case
- The OMS also accepts sponsor-identified opioid overutilization cases

Opioid Overutilization

- Overutilization of Opioid Drugs:
  - Use of opioids with cumulative daily morphine equivalent dose (MED) exceeding 120 mg for at least 90 consecutive days with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims
  - Drug list and conversion factors supported by the Centers for Disease Control and Prevention

Acetaminophen Overutilization

- Overutilization of APAP:
  - Use of APAP with daily dose exceeding 4 g for a total of 30 days or more within any six-month period with at least one day exceeding 4 g within the most recent calendar quarter

Methodology Updates

- Diagnosis Data: Cancer diagnoses are identified via RxHCCs from the Risk Adjustment Processing System dataset, and supplemented with current diagnoses from the Common Working File
- Opioid Methodology: Revised opioid drug list and conversion factors based upon CDC recommendations

OMS Functionality Updates

- January 2014: The OMS was enhanced to collect potential opioid overutilization issues that were identified through Part D sponsors' own internal criteria and reviewed, but not previously identified by CMS
- February 2014: The Medicare Advantage and Prescription Drug System (MARx) collects opioid POS edit data from sponsors and notifies sponsors when a targeted beneficiary changes plans
  - As of October 5, 2015, sponsors submitted 2,020 beneficiary-level opioid POS edits to MARx

Impact of CMS Policy 2011 through 2014 - Opioids

Part D Opioid Overutilization Rates, 2011–2014

Year	Part D Enrollees	Enrollees Using Opioids	% Enrollees Using Opioids	Beneficiaries Exceeding Opioid Outlier Threshold	Change Year-to-Year	Opioid Users Flagged as Outliers
2011	31,483,841	10,049,914	31.9%	29,404	-	0.29%
2013	37,842,632	11,794,908	31.2%	25,347	-4,057	0.22%
2014	39,982,962	12,308,735	30.8%	21,838	-3,509	0.18%

For this comparison, CMS applied the revised opioid methodology, including the expanded drug list from CDC.

Impact of CMS Policy 2011 through 2014 - APAP

Part D APAP Overutilization Rates, 2011–2014

Year	Part D Enrollees	Enrollees Using APAP	% Enrollees Using APAP	Beneficiaries Exceeding APAP Outlier Threshold	Change Year-to-Year	APAP Users Flagged as Outliers
2011	31,483,841	9,449,693	30.0%	76,581	-	0.81%
2013	37,842,632	10,591,651	28.0%	26,122	−50,549	0.25%
2014	39,982,962	10,845,499	27.1%	6,286	−19,836	0.06%

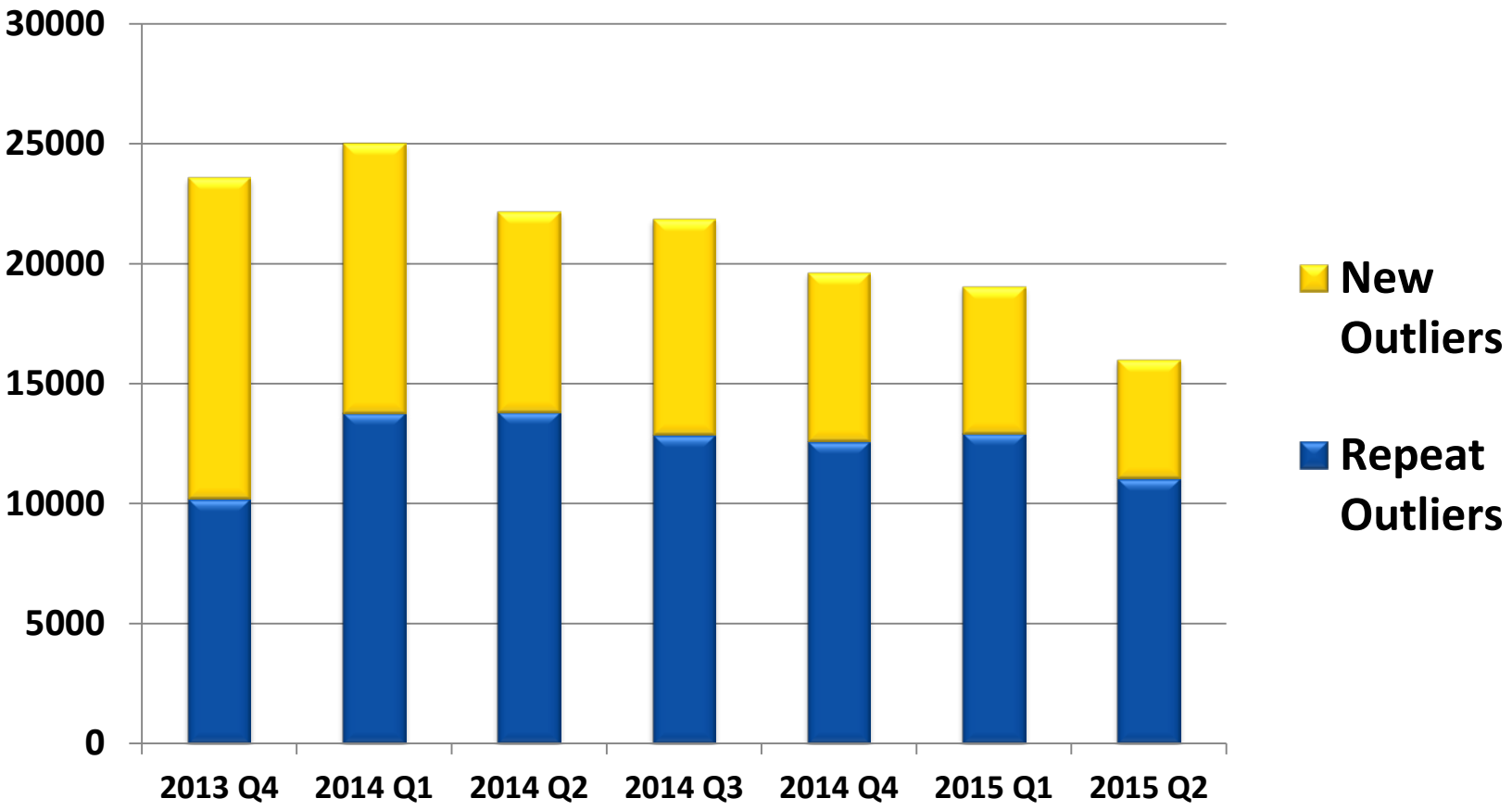
For this comparison, CMS applied the 2014 OMS APAP methodology to all years of service.

Impact of CMS Policy "First-Time" Overutilizers

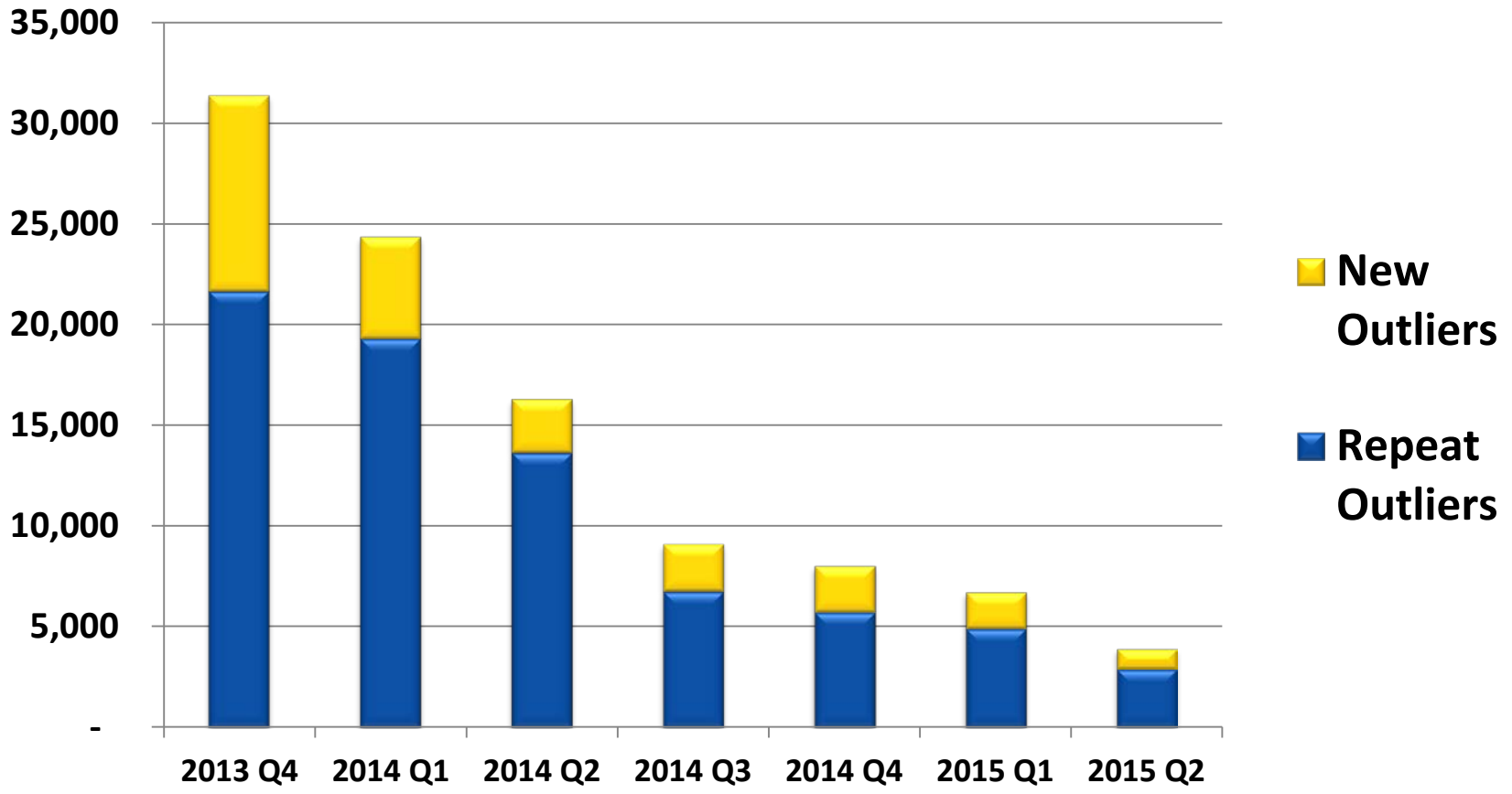
New Potential Overutilizers, Quarterly OMS Cycles

OMS Cycle	New Opioid Outliers	±	% ±	New APAP Outliers	±	% ±
2013 Q4	13,393	-	-	9,758	-	-
2014 Q1	11,279	(2,114)	-15.8%	5,079	(4,679)	-48.0%
2014 Q2	8,369	(2,910)	-25.8%	2,666	(2,413)	-47.5%
2014 Q3	9,002	633	7.6%	2,343	(323)	-12.1%
2014 Q4	7,038	(1,964)	-21.8%	2,302	(41)	-1.7%
2015 Q1	6,128	(910)	-12.9%	1,807	(495)	-21.5%
2015 Q2	4,954	(1,174)	-19.2%	1,009	(798)	-44.2%

Impact of CMS Policy
OMS Quarterly Opioid Tickets



Impact of CMS Policy
OMS Quarterly APAP Tickets



Compliance Outreach

- CMS is performing additional outreach to Part D sponsors who are identified to be outliers based on their responses to the OMS to assess their compliance with CMS guidance
- Sponsors provide additional information about their DUM processes, rationale for their responses submitted to the OMS, and their interventions to prevent overutilization of medications
- Sponsors submit additional information for specific OMS tickets previously processed through the OMS

Summary

- Part D sponsors are in a unique position to identify potential drug overutilization
- Components of improved formulary management
  - POS Safety Edits (Level One)
  - Formulary Management Designs and concurrent DUR (Level Two)
  - Retrospective DUR and Case Management (Level Three)
- Improved drug utilization controls are helping to reduce opioid overutilization in Medicare Part D

Additional Information Resources

- Improving Drug Utilization Controls in Part D (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html)

- Formulary Guidance (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html)

Resources

Questions related to Formulary Management should be directed to: PartDFormularies@cms.hhs.gov

Questions related to general PartD Policy or Opioid Overutilization / OMS should be directed to:

PartD_OM@cms.hhs.gov

Questions related to technical concerns for the OMS or Patient Safety Analysis website should be directed to: PatientSafety@AcumenLLC.com