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

Anna Polk, PharmD

Division of Formulary and Benefit Operations, Medicare Drug Benefit and C&D Data Group, CMS

Diane McNally, RPh, MS

Division of Clinical and Operational Performance, Medicare Drug Benefit and C&D Data Group, CMS

May 5, 2016

Overview

- Overutilization Policy Development
- Improving Drug Utilization Review Controls in Part D
- Formulary Review Process
- Formulary Management Strategies
- Overutilization Activities and Impact of Policy
- Overutilization Policy, 2017 Call Letter

Opioid Epidemic

- From 2000 to 2014 nearly half a million people died from drug overdoses[1]
- At least half of all opioid overdose deaths involve a prescription opioid[1]
- Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled, as did deaths from prescription opioids[2,3]

1. Centers for Disease Control and Prevention. Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014. MMWR 2015; 64;1-5.
2. Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. Available from URL:http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_w#fig2. Accessed August 17, 2015.
3. CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at http://wonder.cdc.gov

How many Americans die daily from an Opioid Overdose ?

A. 13

B. 54

C. 78

D. 115

Overutilization Policy Development

- **Final 2013 Call Letter, April 2, 2012**: Comprehensive policy focused on medication safety to reduce beneficiary overutilization of opioids and to maintain needed access.
- **September 6, 2012**: Final supplemental guidance
- **January 1, 2013**: Sponsors implement new policy in Medicare Part D

Improving Drug Utilization Review Controls in Part D

- **Level One**: Improved Use of Concurrent Claim Edits (Safety Controls at Point of Sale)
- **Level Two**: Improved Use of Formulary Management Designs
- **Level Three**: Improved Retrospective DUR Programming & Case Management

Reference: CY 2013 Final Call Letter

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

Cumulative MED Opioid POS Edit CY 2014 – CY 2016

Year	# of FIDs with a Cumulative MED POS Edit	Total # of FIDs	% of FIDs with a Cumulative POS Edit
2014	0	437	0%
2015	36	467	7.7%
2016	108	456	23.7%
2017	All sponsors expected to implement soft and/or hard formulary-level cumulative opioid morphine equivalent dose (MED) edit at POS. (CY 2017 Final Call Letter)		

Cumulative MED Opioid POS Edit Pilot Project, 2015

- Goal: Assess the feasibility and impact of POS Edits

1. Soft Edit: 100 mg daily MED for at least 60 consecutive days with more than 2 prescribers and more than 2 pharmacies for their opioid prescriptions with exclusions.

2. Hard Edit: Opioid use exceeding 200 mg MED with exclusions.

   – Exclusions included criteria for cancer, hospice care, and prior determinations of medical necessity

Cumulative MED Opioid POS Edit Pilot Lessons Learned

- Part D sponsors effectively implemented either a soft or hard cumulative MED Opioid Edit at POS that excluded known exemptions
- Formal complaints were not received from beneficiaries or providers
- POS Edits were effective at identifying, delaying or altering opioid prescriptions for beneficiaries with potential overutilization while maintaining access

Cumulative MED Opioid POS Edit Pilot Lessons Learned (cont.)

- Minimize False Positives:
  - Exclusions Important:
    - Hospice Enrollment
    - Cancer Diagnoses or Part D Cancer Drug Fill
    - Allowance for Acceptable Refill or Fill Intervals
    - Prior Medical Necessity Determination
    - 'Active' Beneficiary-level POS Edit
  - Inclusion of Prescriber Criterion (or lack of) Impacts Outcomes

Cumulative MED Opioid POS Edit Expectations

- Expect all sponsors to implement soft and/or hard edit for CY 2017 with the following recommendations:
  - Hard: At least 200 mg MED
  - Soft: No lower than 90mg MED
  - Include exclusions
  - Include prescriber count criterion (at least two)
  - Exclude buprenorphine +/- naloxone SL and Buccal formulations for the treatment of opioid use disorder (medication-assisted-treatment, MAT)

Cumulative MED Opioid POS Edit Expectations (cont.)

- Sponsors also expected to implement soft-edit for the concurrent dispensing of an opioid with buprenorphine for opioid use disorder
  - Should only implement this edit if they have the technical ability to not reject buprenorphine claims

Cumulative MED Opioid POS Edit Formulary Requirements

- If the only quantity restriction is the cumulative MED edit, a QL does NOT need to be reflected on HPMS formulary submission
  - Include a QL on the HPMS formulary submission for all formulary opioids that have a QL that is below any applicable FDA-approved maximum dose
- Non-formulary opioids can also be included in the cumulative MED Edit
- Submit details to CMS by September 1, 2016
  - Template will be provided by CMS

Reference: CY 2017 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

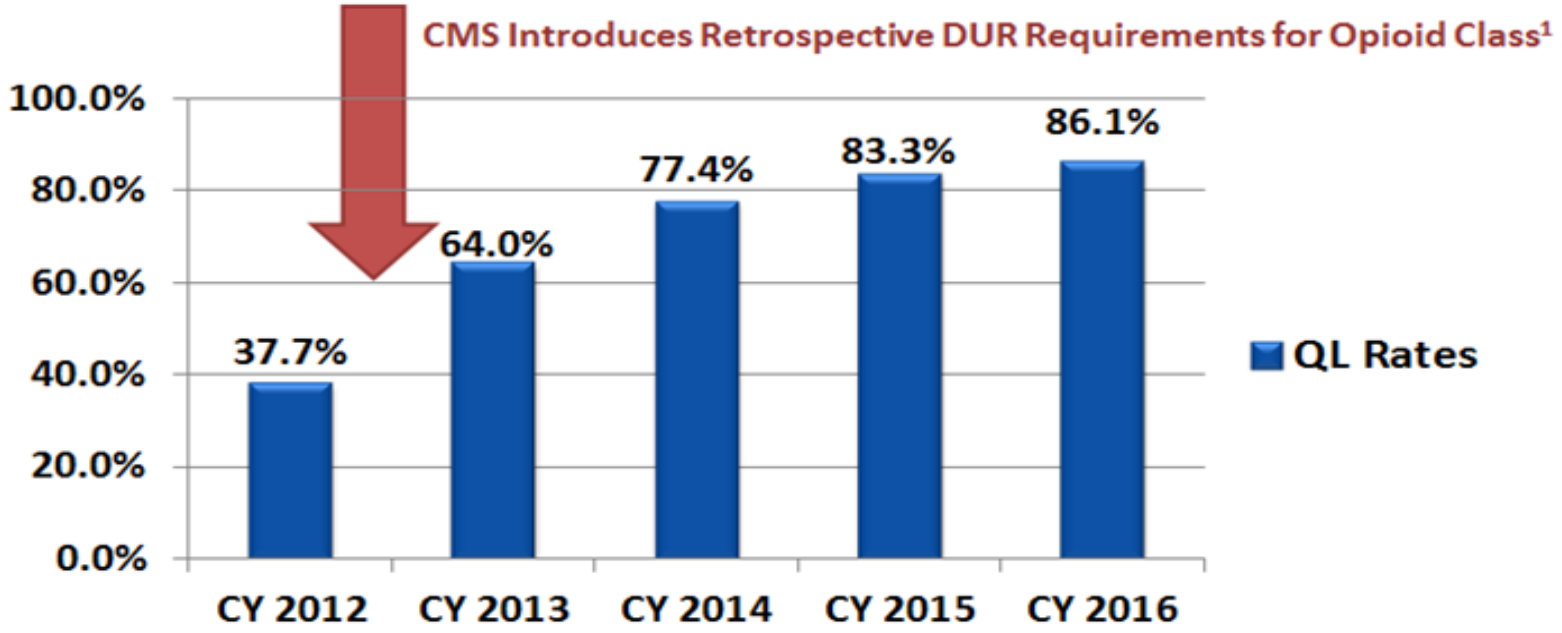
Background: Part D Formulary Review Process

- Formularies are submitted and reviewed via the Health Plan Management System (HPMS)
  - Submissions are based on RXCUIs, adopted from National Library of Medicine's RxNorm system, to represent distinct brand names, generic names, strengths, routes of administration, and dosage forms of drugs
  - Each RXCUI must be flagged with all applicable PA/ST/QL restrictions
- One formulary (FID) can be used across multiple plans

What was the Percent Increase in Opioids with QL Since 2012?

- 25%
- 51%
- 98%
- 128%

Percent of Opioid RxCUIs on Part D Formularies with QL, 2012-2016



Source: CY 2012-2016 HPMS approved formulary data

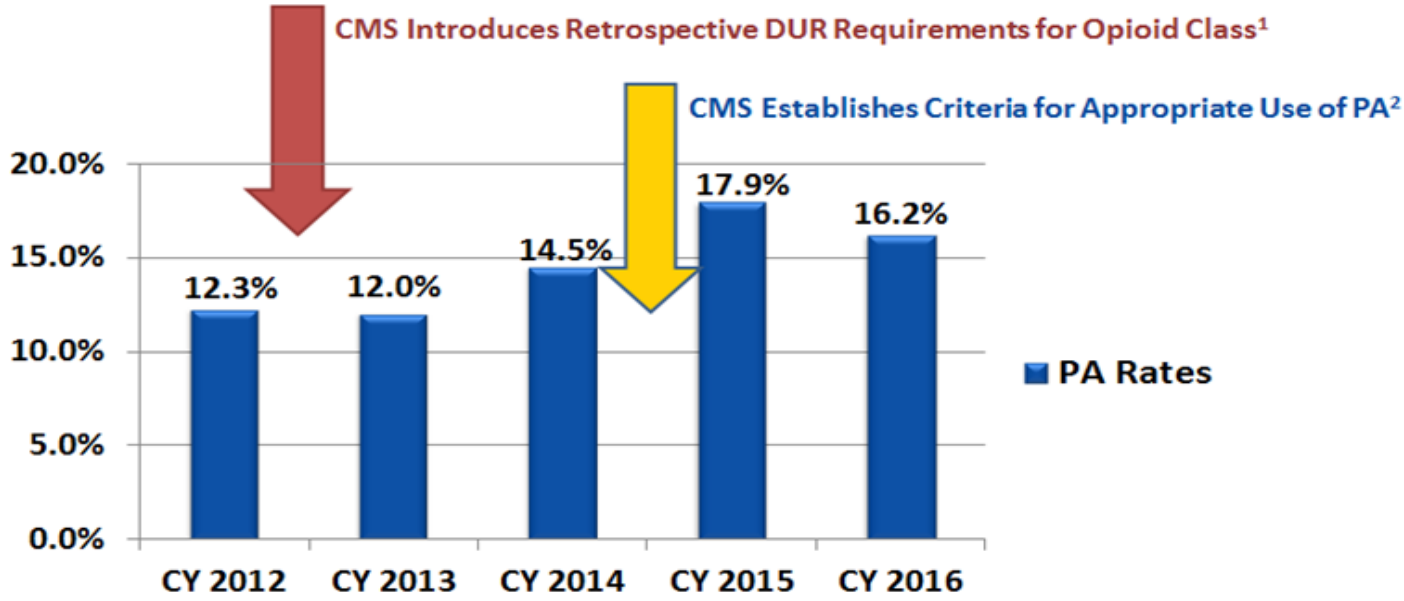
1. CY 2013 Call Letter

QL Rate Changes for Opioid Drugs CY 2012 – CY 2016

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: CY 2012-2016 HPMS approved formulary data

Percent of Opioid RxCUIs on Part D Formularies with PA, 2012-2016



Source: CY 2012-2016 HPMS approved formulary data

1. CY 2013 Final Call Letter

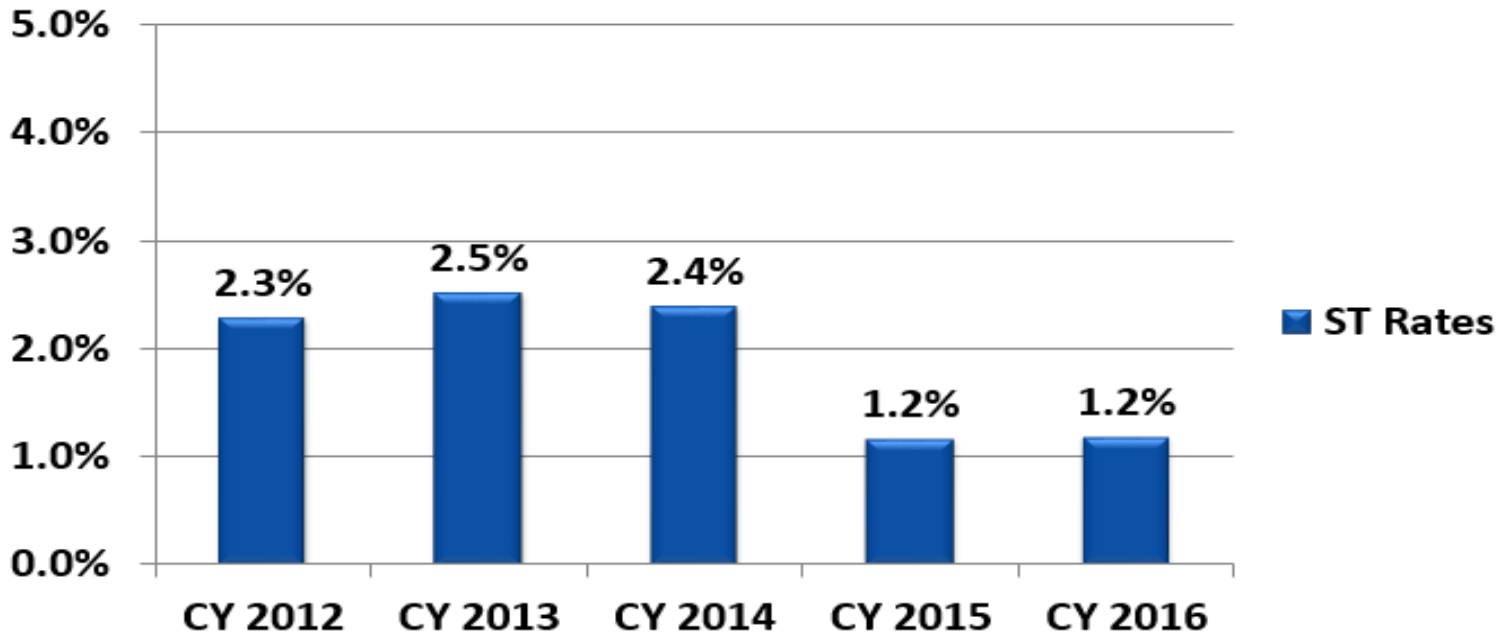
2. CY 2015 Final Call Letter

PA Rate Changes for Opioid Drugs CY 2012 – CY 2016

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: CY 2012-2016 HPMS approved formulary data

Percent of Opioid RxCUIs on Part D Formularies with ST, 2012-2016



Source: CY 2012-2016 HPMS approved formulary data

Overutilization Activities & Impact of Policy

- Level Three DUR – Beneficiary-level MARx Opioid POS Edit
- Overutilization Monitoring System (OMS)
- Part D Sponsor Compliance Outreach
- Key Findings

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
  - Beneficiary-specific point of sale (POS) edits to prevent Part D coverage of opioid overutilization, if necessary

Reference: CY 2013 Final Call Letter

Beneficiary-level Opioid POS Edit Determination Process

- Prescriber reaction to case management drives plan sponsor response
- Sponsor communicates with prescribers to determine medical necessity, consensus reached:
  - One prescriber agrees to manage opioid therapy
  - Monitor use
  - Implement beneficiary-level POS Edit(s)
- Non-responsive prescribers
  - Implement beneficiary-level POS Edit(s) with P&T committee input

Beneficiary-Level Opioid POS Edit MARx Database

- Implemented: February 8, 2014
- Actions: Sponsor submits beneficiary-level POS Edit information into MARx
- Purpose: Automates data-sharing between Part D sponsors; removes beneficiaries with 'Active' POS Edit from OMS reports for 1 year

Submission of Beneficiary-level Opioid POS Edit to MARx

- New Beneficiary-level POS Edit, submit to MARx (User Interface or Batch)
  - Beneficiary Demographics
  - Notification Date (within 7 business days)
  - POS Edit Code
  - Submit New Decisions (within 7 business days)
    - Change in POS Edit Code (PS1 to PS2)
    - Add Implementation Date
    - Add Termination Date
- 'Active' Beneficiary-level POS Edit notification from Daily Transaction Reply Report (DTRR)

Impact of Policy: Beneficiary-level Opioid POS Edits Through 4/06/2016

- 188 Unique Contract Submissions
- 2564 Unique HICNS
- 85% of Beneficiaries are less than 65 years old
- 3% and 6% of Beneficiaries Dis-enrolled within 30 and 60 days of Notification
  - About 8% switch plans and the edit is continued
- 57% of Notified Beneficiaries have an ‘Active’ Edit, Associated with 126 Contracts

Overutilization Monitoring System (OMS)

- Implemented: July 2013
- Purpose: Oversight of sponsors' compliance with CMS' overutilization policy
- Reports: Part D sponsors are provided quarterly reports identifying potential opioid and APAP over-utilizers
- Action: Sponsors submit the outcome of their review of each case and submit results of internally identified over-utilizers

OMS Overutilization Definitions

- **Opioids**: 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, excluding beneficiaries with cancer or receiving hospice care
- **Acetaminophen (APAP):** Total of 30 days or more of APAP exceeding 4 g within any six-month period in the last year with at least one day exceeding 4 g within the most recent calendar quarter
- **CPI Referrals**: Beneficiaries referred by the Medicare Center for Program Integrity for review of potential utilization issues

Impact of CMS Policy
2011 through 2015 - Opioids

Part D Opioid Overutilization Rates, 2011–2015

Year	Total Part D Enrollees	Part D Enrollees Using Opioids	% Part D Enrollees Using Opioids	Opioid Potential Overutilizer Enrollees	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	0.21%
2014	39,982,962	12,308,735	30.8%	21,838	-3,509	0.18%
2015	41,835,016	12,510,448	29.9%	15,651	-6,187	0.13%

47% decrease

57% decrease

Reference: CY 2017 Final Call Letter

Overutilization Activities Compliance Outreach

- Objectives: (1) Assess sponsors' compliance with CMS guidance to prevent overutilization of prescribed medications; (2) Explore potential revisions to policy guidance or overutilization criteria
- Selection: Eight parent organizations (POs) with more than 1,000 APAP and opioid tickets-October 2014 OMS
- Evaluation:
  - High rate of specific responses
  - Low rate of POS Edits
  - High rate of repeat responses

Compliance Outreach Findings

- Action: POs asked for information on:
  - In general, what are your internal criteria for identifying potential opioid overutilization?
  - More specifically, which criteria were not met for the tickets provided? Please provide a detailed response.
- Conclusion:
  - Sponsors generally compliant with CMS guidelines.
  - Opportunities to modify opioid overutilization criteria to reduce false positives.

Compliance Outreach Findings (cont.)

- Reasons why a beneficiary did not meet the sponsor's internal criteria or the overutilization was resolved:
  - Prescriber and/or pharmacy counts not met
  - Situational acute event
  - Opioid regimen consistent and no evidence of early refills
  - Overutilization decreased during more recent months

Compliance Outreach Findings (cont.)

- Potential lack of POS Edit
  - Direct communication with providers and monitoring for behavior post-outreach impacts a member's opiate utilization
  - Outreach process goal is to encourage an individual prescriber to self-identify, coordinate care
- Next Steps: CMS will analyze options to potentially modify the opioid overutilization criteria (with consideration of the CDC Guideline) for discussion in the 2018 Call Letter.

Overutilization Policy 2017 Call Letter

- Opioid Use Monitoring
  - Investigate modifications to opioid potential over-utilizer criteria (2018)
    - Incorporate CDC Guideline for Prescribing Opioids for Chronic Pain
    - Investigate prescriber same practice groupings
  - Add contract-level opioid high-daily dose rate (OMS, 2016)
- APAP Use Monitoring
  - Remove OMS potential APAP over-utilizers reporting (4/2016)
  - Add contract-level APAP high-daily dose rate to Patient Safety reports (2016), Outlier report (2017)

Additional Priorities 2017 Call Letter

- Implementation of prospective soft and hard formulary-level opioid POS claim edits based on cumulative MED, and a soft opioid POS claim edit following initiation of buprenorphine for opioid use disorders
- Timely submission by Part D sponsors of beneficiary-level opioid POS edit data to MARx (7 business days)
- Maintain formulary access to medication-assisted treatment for opioid use disorders
- Eliminate sponsors' utilization management processes that may lead to inappropriate use of methadone in pain management

Conclusion

- Improved drug utilization controls are helping to reduce opioid overutilization in Medicare Part D
- Part D sponsor's use of DUM controls have reduced the dispensing of high doses of APAP
- Cumulative opioid POS Edits with exclusions are feasible and effective
- Majority of studied Part D parent organizations are compliant with CMS opioid criteria
- Sponsors use beneficiary POS Edits sparingly (after case management)

Additional Information Resources

- Improving Drug Utilization Controls in Part D
  (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html)
- Plan Communication User Guide (PCUG)
  (https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Plan_Communications_User_Guide.html)
- Formulary Guidance
  (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html)
- CDC Guideline for Prescribing Opioids for Chronic Pain
  (http://www.cdc.gov/drugoverdose/prescribing/guideline.html)

Resources

Questions related to:

- Formulary Management go to: PartDFormularies@cms.hhs.gov
- MARx / Opioid Overutilization / OMS go to: PartD_OM@cms.hhs.gov
- Technical concerns for the OMS or Patient Safety Analysis website go to: PatientSafety@AcumenLLC.com