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CARA/Opioids

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Medicare Part D Opioid Overutilization Strategies for 2019:

Implementation of CARA and Other Policy Guidance

Topics

- 2019 Part C and D Regulation – CARA Drug Management Programs
- 2019 Call Letter Updates – Part D Opioid Overutilization Guidance
- Impact of Part D Policy

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Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf

As required by the Comprehensive Addiction and Recovery Act (CARA), in this final rule, CMS finalized the framework under which Part D plan sponsors may voluntarily adopt drug management programs for beneficiaries who are at risk of misusing or abusing frequently abused drugs.

Drug Management Programs – General Structure

- Integrated with the existing Medicare Part D Overutilization Monitoring System (OMS)
- Clinical Guidelines/OMS Criteria to Identify Program Size of Potential At-Risk Beneficiaries (PARBs)
- Frequently Abused Drugs (FADs) for purposes of Drug Management Programs
- Exempted Beneficiaries

Drug Management Programs – General Structure (continued)

- Written Policies and Procedures
- Case Management/Clinical Contact/Prescriber Verification/ Reporting to CMS
- Overutilization Tools for At-Risk Beneficiaries (ARBs), if Needed:
  - Limitation on Access to Coverage for FADs through Lock-In to Selected Pharmacy(ies)/Prescriber(s)
    - Beneficiary Preferences/Exceptions; Reasonable Access
  - Beneficiary-Specific Point-of-Sale (POS) Claims Edits for FADs
- Beneficiary Notices
- Beneficiary Appeals
- Termination/Extension of Lock-In and POS Edits

Drug Management Programs – 2019 Clinical Guidelines/Program Size

- ***Minimum Criteria*** *(Sponsors must review PARBs)*
  - ≥ 90 morphine milligram equivalent (MME) AND either
  - 3+ opioid prescribers AND 3+ opioid dispensing pharmacies OR
  - 5+ opioid prescribers AND 1+ opioid dispensing pharmacies
  - Currently estimate 44,332 PARBs will be identified
- ***Supplemental Criteria*** *(Sponsors may review as many PARBs as manageable)*
  - Any Level MME AND
  - 7+ opioid prescribers OR 7+ opioid dispensing pharmacies
  - Currently estimate 22,841 PARBs will be identified

Drug Management Programs – Frequently Abused Drugs (FADs)

- ***FADs = Opioids and Benzodiazepines***
  - Except for buprenorphine for medication-assisted treatment (MAT) and injectables
- ***Note about OMS criteria and FADs***
  - PARBs are identified by opioid use, but coverage limitations can apply to all FADs
  - Final regulatory definitions of clinical guidelines and FADs contain standards which the OMS criteria and FADs must meet; this structure allows CMS to update the OMS criteria and drugs that constitute FADs through the annual Parts C&D Call Letter process, as long as these standards are met

Drug Management Programs – Exempted Beneficiaries

- An **exempted beneficiary**
  - Has elected to receive hospice care or is receiving palliative or end-of-life care, or
  - Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which FADs are dispensed for residents through a contract with a single pharmacy, or
  - Is being treated for active cancer-related pain

Drug Management Programs – Case Management/ Clinical Contact/Prescriber Verification

- The final rule requires Part D plan sponsors' clinical staff to perform case management for each PARB for the purpose of engaging in clinical contact with the prescribers of FADs and verifying whether a PARB is an ARB
- Based on information obtained during case management, plan sponsor makes the determination whether a PARB is an ARB

Drug Management Programs – Requirements for Limiting Access to Coverage of FADs

- Case management
- Prescriber agreement (except when not required), and
- Beneficiary notice required before limiting ARB's access to coverage of FADs

Coverage Limit	Prescriber Verification of At-Risk Status	Prescriber Agreement for Coverage Limitation (Initial 12 Months)	Prescriber Agreement for Coverage Limitation (Extend Additional 12 Months)
POS Edit	Yes**	Yes**	Yes**
Pharmacy Lock-In	Yes**	No*	No*
Prescriber Lock-In	Yes***	Yes***	Yes***

*If prescriber rejects pharmacy lock-in, the plan should take this into consideration
**If prescriber does not respond to case management, the plan may proceed with limitation
***If prescriber does not respond to case management, the plan cannot proceed with prescriber lock-in

Drug Management Programs – At-Risk Determinations

- An at-risk determination is a decision made under a plan sponsor's drug management program that involves:
  - Identification as an ARB for prescription drug abuse
  - A limitation, or the continuation of a limitation, on access to coverage for FADS
  - Information sharing for subsequent plan enrollments
- Once an enrollee is identified as at-risk, the enrollee will receive a second written notice that explains the limitations and appeal rights
- If a limitation is continued beyond the initial 12-month period, the enrollee will receive an additional second notice

Drug Management Programs – Beneficiary Notices and Timeframes *(1 of 5)*

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Initial Notice includes:

- Notice to beneficiary that plan sponsor has identified them as a PARB and the proposed coverage limitation on their access to FADs
- 30 days for the PARB to submit relevant information and preferences for selected pharmacy/prescriber, in the case of a proposed lock-in
- Timeframe for plan sponsor’s decision
- Information on any limitation on the availability of the LIS SEP, if applicable

Drug Management Programs – Beneficiary Notices and Timeframes *(2 of 5)*

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Second Notice includes:

- Notice that plan sponsor has identified them as an ARB
- Coverage limitation on access to FADs with effective and end dates
- Selected pharmacy(ies)/prescriber(s), or both, if applicable, from which the beneficiary must obtain FADs for coverage by plan
- Explanation that beneficiary may still submit preferences for selected pharmacy/prescriber, in the case of lock-in
  - Note: Plan sponsor must send additional written notice with new pharmacy(ies)/prescriber(s) within 14 days after receipt of submission
- Information on any limitation on the availability of the LIS SEP, if applicable
- Explanation of the beneficiary's right to a redetermination

Alternate Second Notice informs the beneficiary that:

- Plan sponsor has not identified them as an ARB
- Plan sponsor will not implement a coverage limitation
- SEP limitation no longer in effect, if applicable

The plan sponsor must provide a Second Notice or Alternate Second Notice to the beneficiary

- No less than 30 days and
- Not more than the earlier of:
  - The date that the sponsor makes the relevant determination, or
  - 60 days after the date of the Initial Notice

Drug Management Programs – Beneficiary Notices and Timeframes (plus Exception) (5 of 5)

Example 1

- March 1, 2019: Initial Notice provided for pharmacy lock-in
- March 30, 2019: PARB submits a pharmacy preference
- April 15, 2019: Plan sponsor provides Second Notice confirming pharmacy lock-in to end April 14, 2020

Example 2

- March 1, 2019: Initial Notice provided for prescriber lock-in
- March 21, 2019: PARB submits evidence showing they do not meet clinical guidelines
- April 1, 2019: Plan sponsor provides Alternate Second Notice that it will not implement prescriber lock-in

Exception: No Initial Notice required for an ARB who switched plans if the POS edit or, in the case of lock-in, the selected pharmacy or prescriber is the same

Drug Management Programs – LIS SEP Limitation (1 of 3)

- Starting 1/1/2019, duals/LIS SEP only used once per calendar quarter
  - Only allowed in quarters 1, 2, and 3
  - Annual Enrollment Period (AEP) can be used in quarter 4
- Individuals notified they are a PARB or an ARB under a drug management program can't use the duals/LIS SEP to change plans
- Other election periods still available – AEP, other SEPs, which the individual meets the criteria to use

Drug Management Programs – LIS SEP Limitation (2 of 3)

- Notification – Once identified as a PARB, sponsor provides an Initial Notice with SEP limitation

- Effective as of the date on the Initial Notice

Drug Management Programs – LIS SEP Limitation (3 of 3)

- Duration: If sponsor takes no additional action within 60 days to identify an individual as an ARB, the SEP limitation ends
- Limitation lasts:
  - As long as individual is enrolled in that plan, or
  - Until the “at-risk” determination is successfully appealed, or
  - When the status expires or is terminated by the plan –
    - Initial 12-month period
    - Plan’s option to extend for a maximum of 24 months in total upon reassessment of the at-risk status

Drug Management Programs – Beneficiary Preferences (Exceptions) and Reasonable Access (1 of 2)

- In the case of lock-in, plan sponsor must accept beneficiary's pharmacy/prescriber preferences (as long as in-network), unless an exception applies
- Exception to beneficiary preferences if:
  - Plan sponsor determines that selection would contribute to drug abuse or diversion; and
  - There is strong evidence of inappropriate action by the prescriber, pharmacy, or beneficiary
- Plan sponsor must provide beneficiary with 30 days advance written notice and a rationale if the sponsor changes the selections

Drug Management Programs – Beneficiary Preferences (Exceptions) and Reasonable Access (2 of 2)

- When plan sponsor selects the pharmacy/prescriber, sponsor must ensure beneficiary has reasonable access to FADs taking into account all relevant factors
- Reasonable access may necessitate selection of more than one pharmacy/prescriber or an out-of-network pharmacy or prescriber

Drug Management Programs – Termination/ Extension of At-Risk Status *(1 of 2)*

Identification as an ARB terminates as of the earlier of:

- Date beneficiary demonstrates they are no longer an ARB without the coverage limitation for FADs
- End of a one-year period unless the limitation was extended for an additional year
- End of a two-year period, if the limitation was extended

Drug Management Programs – Termination/ Extension of At-Risk Status (2 of 2)

To extend a limitation, plan sponsor must:

- Determine that there is a clinical basis for the extension
- Obtain the agreement of a prescriber of FADs for extension
  - Note: Not required for pharmacy lock-in; not required for a beneficiary-specific POS edit if no prescriber is responsive
- Provide a Second Notice to the beneficiary

Appeal of At-Risk Determinations

- At-risk determinations are subject to the existing Part D benefit appeals process
- If an enrollee disagrees with an at-risk determination made under a plan's drug management program, the enrollee has the right to request a redetermination
- The enrollee has 60 days from the date of the second notice to request an appeal, unless there is good cause for late filing
- All disputes raised in an appeal request must be adjudicated as a single case

Part D Benefit Appeals Process

- Appeals of at-risk determinations are subject to the standard and expedited appeals processes
- Standard Timeframes
  - Redetermination – 7 days
  - Reconsideration – 7 days
- Expedited Timeframes
  - Redetermination – 72 hours
  - Reconsideration – 72 hours
- In all cases, the enrollee must be notified of the decision as expeditiously as the enrollee's health condition requires

Changes to At-Risk Determinations

An at-risk determination made under a drug management program can be changed by:

- The appeals process – An enrollee, an enrollee's representative, or their prescriber may dispute an at-risk determination and a change is made on appeal
- A new at-risk determination made by a plan sponsor – As a result of ongoing case management, a plan sponsor may make a new at-risk determination that changes a previous limitation

Coverage Determinations

In addition to the right to appeal an at-risk determination, an enrollee always has the right to request a coverage determination, including an exception, for a drug he or she believes may be covered.

Plan Sponsor Redeterminations

- In notifying an enrollee of a redetermination of an at-risk determination, a plan sponsor may use CMS' model Redetermination Notice or develop their own notice
- An adverse redetermination decision must clearly and specifically explain the reason for the denial and include an explanation of the enrollee's right to appeal to the IRE
- Favorable decisions must clearly explain the conditions of approval
- Changes made by a redetermination (or higher level of appeal) must be effectuated using the existing effectuation requirements for Part D benefit requests

Other Changes for 2019

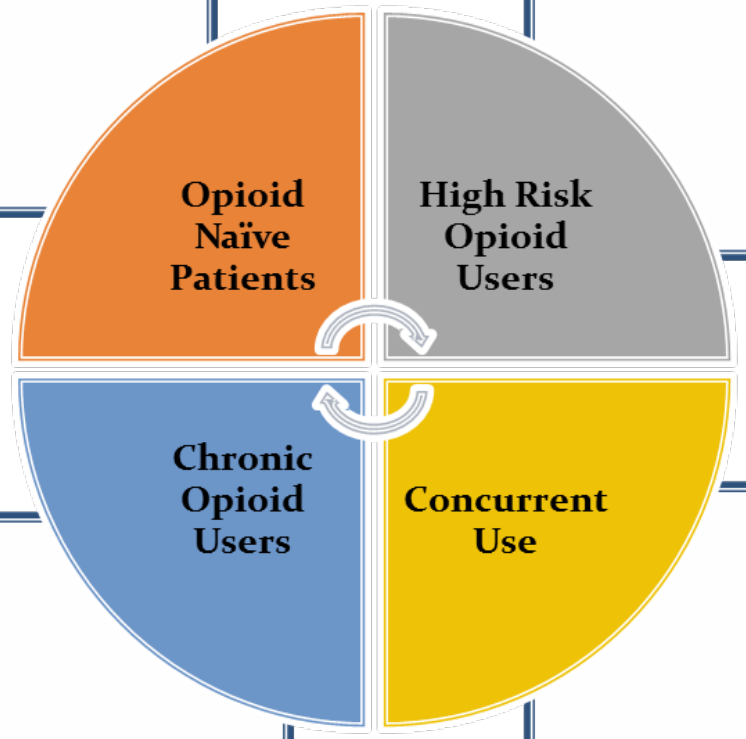
- **2019 Medicare Parts C&D Call Letter**
  https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html

- Effective January 1, 2019, CMS announced new strategies to further help Medicare Part D plan sponsors prevent and combat opioid overuse.

2019 Opioid Overutilization Guidance

- 7 days supply hard edit on initial opioid prescription fills (acute pain)

- OMS/CARA drug management program
- Revised OMS metrics
- Information on concurrent potentiator drug use



- 90 MME opioid care coordination edit
- High MME hard edit (Optional)

- Duplicate LA opioid therapy soft edit
- Concurrent benzodiazepine-opioid soft edit

Beneficiary Protections

- Beneficiaries who are residents of a long-term care facility, in hospice care or receiving palliative or end-of-life care, or being treated for active cancer-related pain should be excluded
- Beneficiaries' access to medication-assisted treatment (MAT), such as buprenorphine, should not be not impacted
- For claims not resolved at point of sale, beneficiaries must receive written copy of standardized CMS pharmacy notice explaining their right to request a coverage determination

Safety Edit Pilot

- Goal: Conduct a small, informal pilot in 2018 to develop best practices/technical guidance for opioid naïve 7 days supply limit and care coordination safety edits
- Recruit Part D plan sponsor volunteers (~3) to help pilot test/share feedback with CMS, such as:
  - Test coding/specifications
  - Assess information on provider education, and/or
  - Test pharmacy preparedness
- Interested parties: Email PartD_OM@cms.hhs.gov

Timeline

Date	Activity
May 2018	Recruit safety edit pilot volunteers; Develop design
June-August 2018	Conduct safety edit pilot; Hold regular calls
Fall 2018	Release additional technical guidance as needed – New opioid strategies for 2019, CARA drug management programs, and OMS and MARx system changes
January 2019	Implement new policies

Quality Measures

- Driving performance improvement through quality metrics

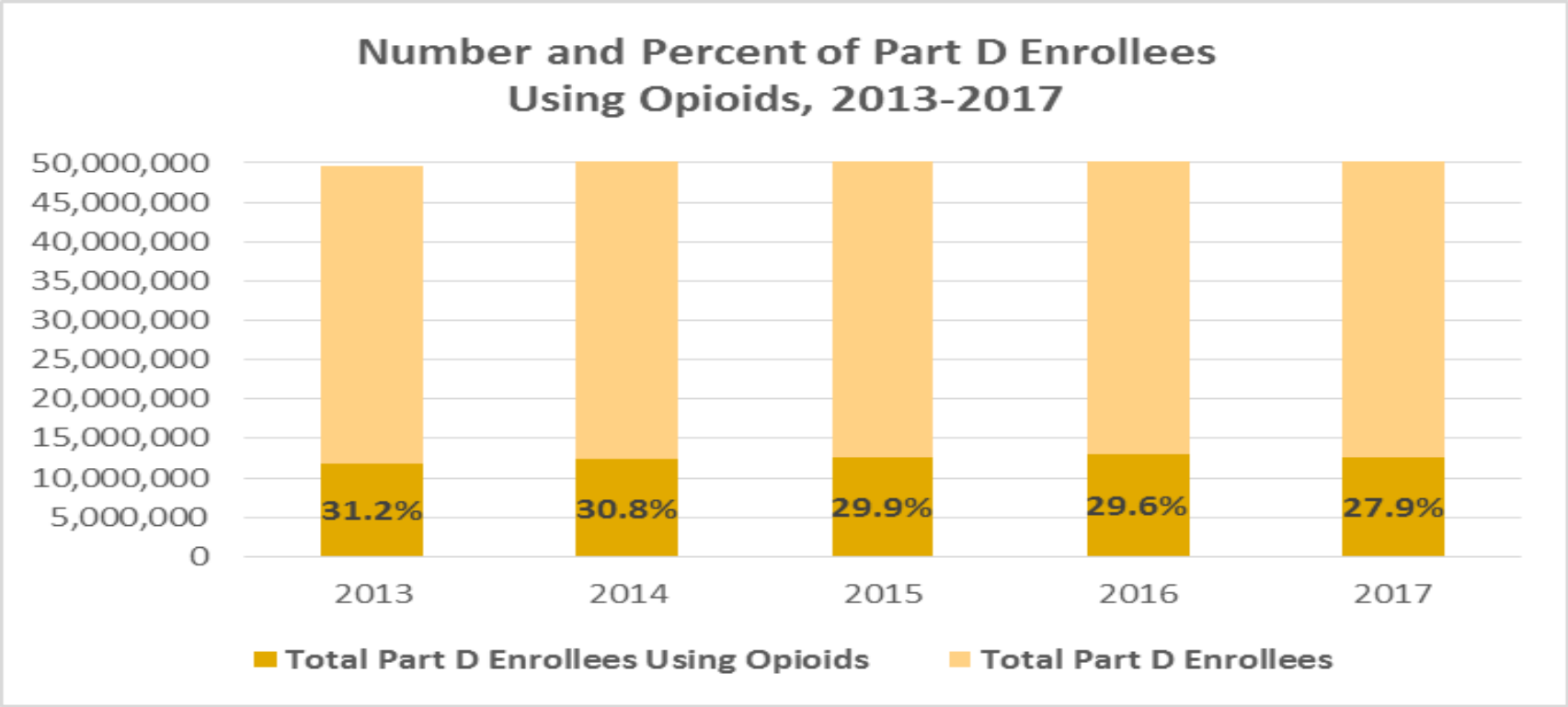
PQA Use of Opioids at High Dosage / Multiple Providers

- Continue to report three measures through Patient Safety Reports
- Implement technical revisions
- Add one measure to 2019 Display Page (using 2017 data)

PQA Concurrent Use of Opioids and Benzodiazepines

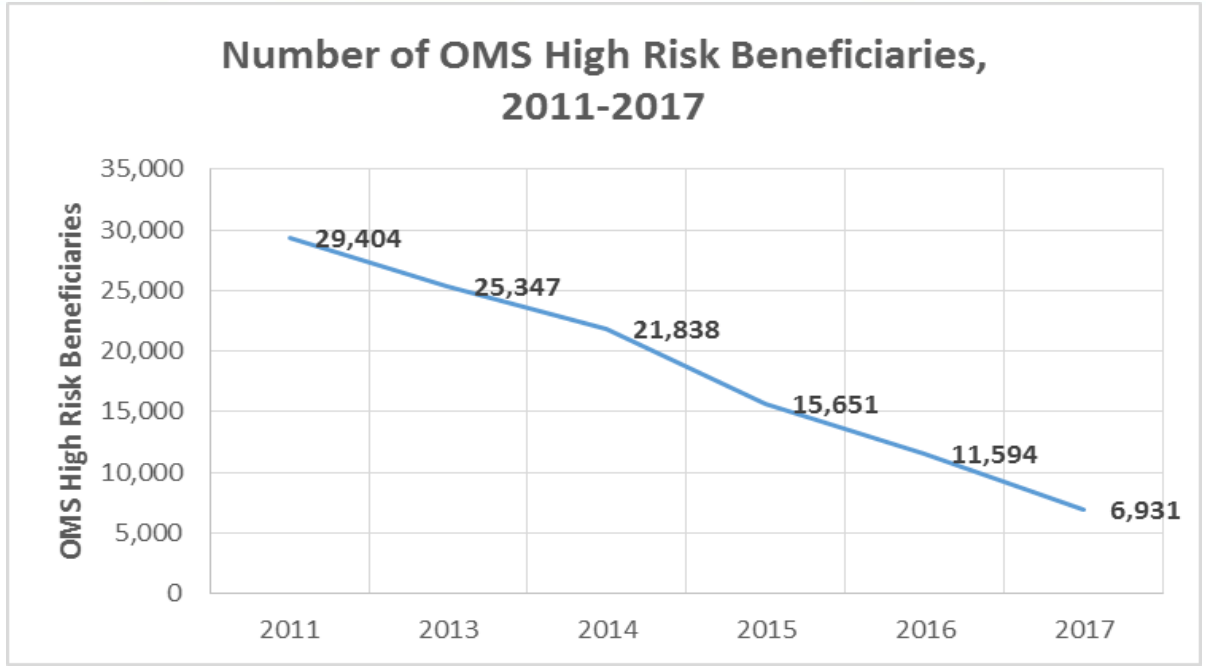
- Begin to report through Patient Safety Reports (2018 Reports launched in April 2018)
- Plan to add to Display Page: 2021 (2019 data) & 2022 (2020 data); Consider for future Star Ratings (pending rulemaking)

Reduction in Share of Part D Enrollees Using Opioids



Source: Table 27 in 2019 Call Letter; Hospice and cancer patients excluded from opioid utilizer counts

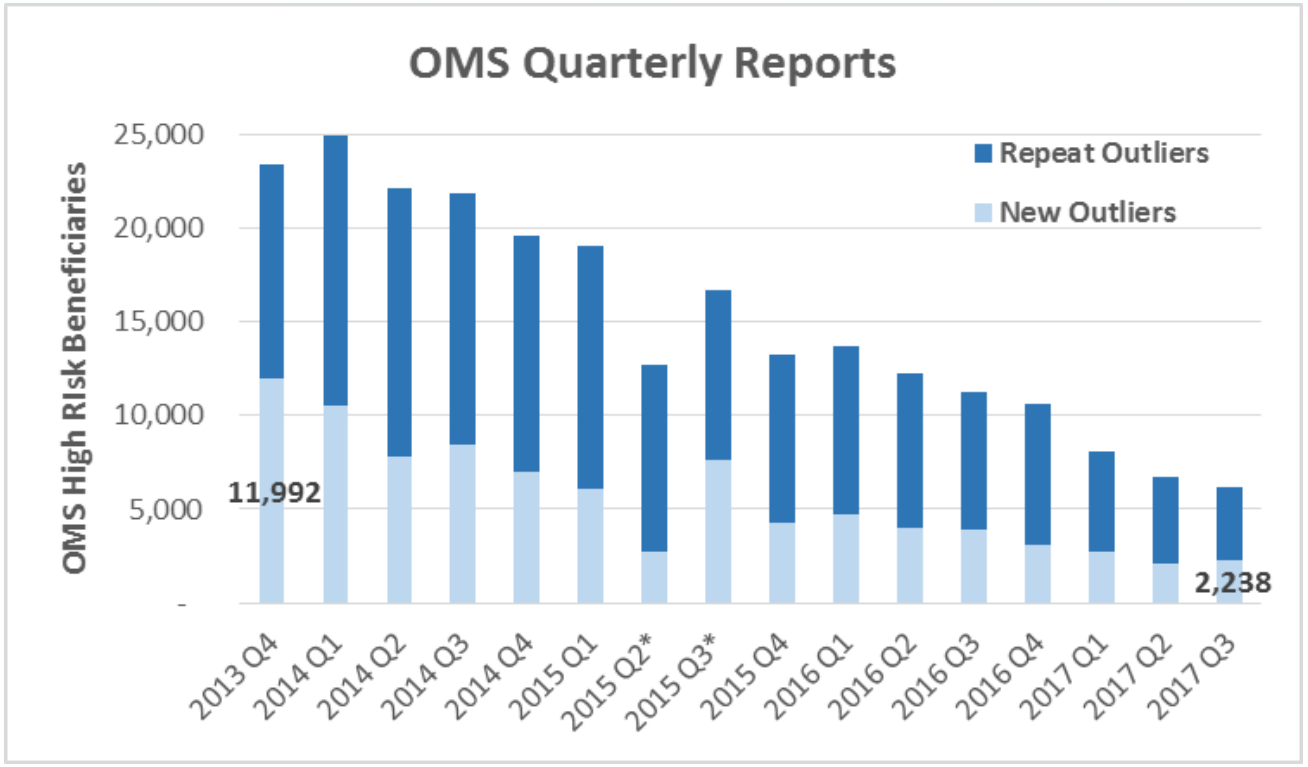
Impact of Policy, OMS



Number of potential high-risk opioid overutilizers decreased by 76%

Source: Table 27 in 2019 Call Letter; 2011 = pre-policy/pilots; 2013 – 2017 OMS criteria: During previous 12 months, > 120 MME for at least 90 consecutive days with more than 3 opioid prescribers and more than 3 opioid dispensing pharmacies contributing to their opioid claims, excluding beneficiaries with cancer and in hospice

Impact of Policy, OMS, "First-Time" Overutilizers

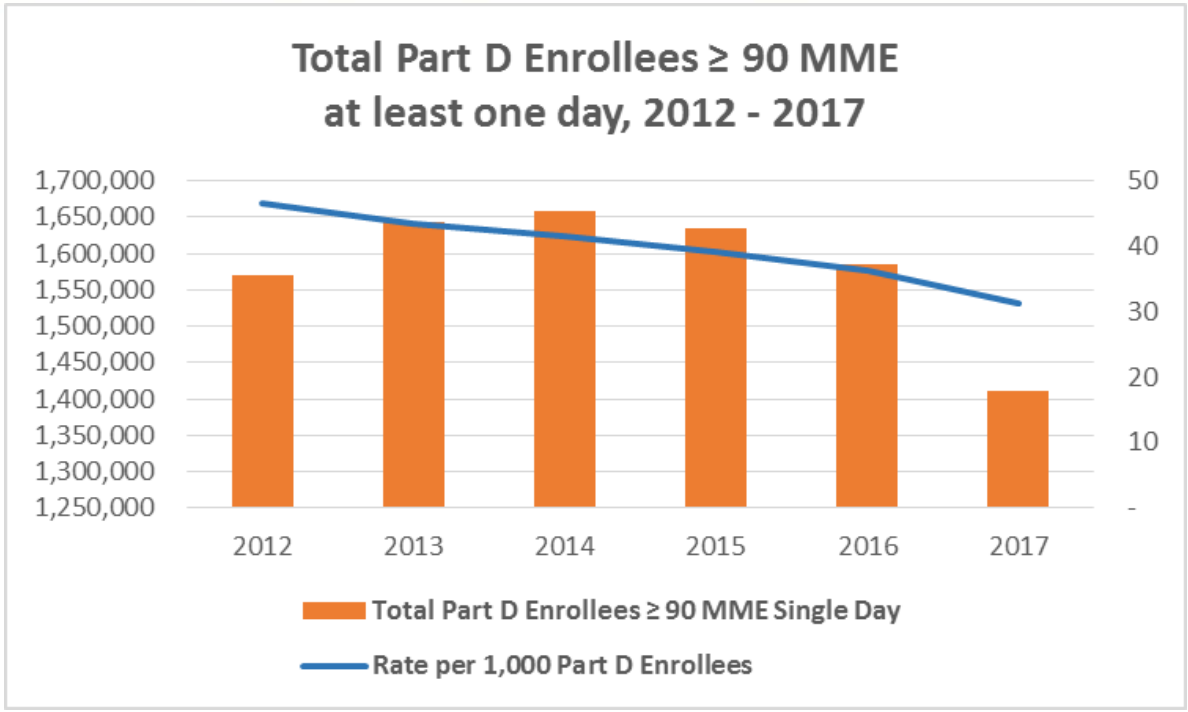


Number of "first-time" potential high-risk overutilizers decreased by 81%

Source: CMS OMS Quarterly Reports; *PDE data load lag issue Q2 2015-Q3 2015

Impact of Policy, 90 MME Levels

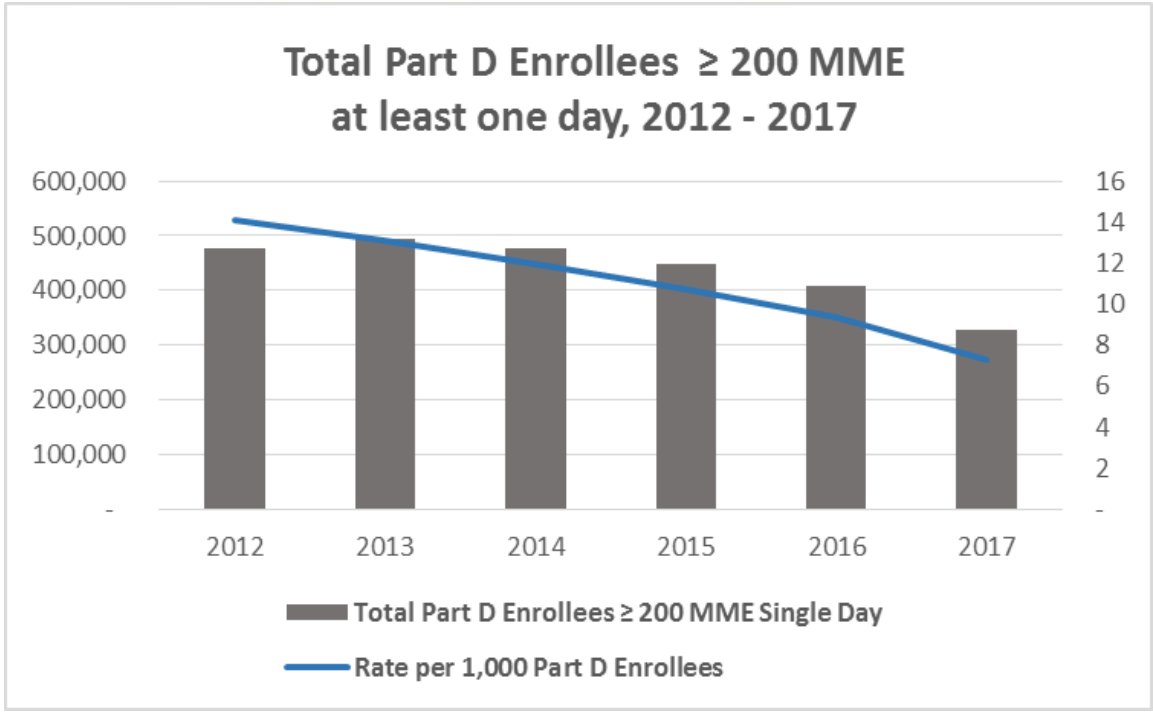
33% decrease in rate of Part D enrollees meeting or exceeding 90 MME for at least one day from 2012 to 2017



Source: 2012 – 2016 SAF; 2017 PDE data as of 3/26/2018; Excluding beneficiaries with cancer, in hospice, or with overlapping dispensing dates for timely continued fills for the same opioid

Impact of Policy, 200 MME Levels

49% decrease in rate of Part D enrollees meeting or exceeding 200 MME for at least one day from 2012 to 2017



Source: 2012 – 2016 SAF; 2017 PDE data as of 3/26/2018; Excluding beneficiaries with cancer, in hospice care, or with overlapping dispensing dates for timely continued fills for the same opioid

Additional Information

- Part D Opioid Overutilization Policy Guidance: (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html)
- Part D Appeals Guidance: Chapter 18 of the Prescription Drug Benefit Manual: (https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip)

Additional Information (continued)

- Eligibility & Enrollment Guidance – Medicare Prescription Drug Benefit Manual:

  Chapter 2 – MAPD
  https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/CY_2018_MA_Enrollment_and_Disenrollment_Guidance_6-15-17.pdf

  Chapter 3 – Part D
  https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicarePresDrugEligEnrol/Downloads/CY_2018_PDP_Enrollment_and_Disenrollment_Guidance_6-15-17.pdf

Questions?

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- Questions related to Part D appeals process should be directed to: PartD_Appeals@cms.hhs.gov
- Questions related to Part D opioid overutilization policy/OMS should be directed to: PartD_OM@cms.hhs.gov
- Questions related to technical concerns for OMS should be directed to: PatientSafety@AcumenLLC.com
- Questions related to Part D Enrollment & Eligibility policy should be directed to: PDPENROLLMENT@cms.hhs.gov