

AMCP Summary: *Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter*

Released: February 1, 2017

Comments Due: March 3, 2017

The Centers for Medicare and Medicaid Services (CMS) released [2018 Draft Call Letter](#) on February 1, 2017. Overall, the Draft Call Letter does not contain any major changes that are of serious concern to managed care pharmacy. However, there are several provisions worth noting, such as changes to Star Ratings and efforts to reduce opioid overutilization, that AMCP is seeking feedback on from its members to inform the comments that will be submitted to CMS.

Comments on this proposal must be submitted to CMS by March 3, 2017 at 6pm ET. AMCP will work with stakeholders to develop comments to CMS to ensure the perspective of managed care pharmacy is voiced as changes to payment policies and the Star Ratings are considered. You may provide feedback via email to Soumi Saha, Assistant Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by Tuesday, February 28th on any of the provisions included in the Draft Call Letter. AMCP's final comments to CMS will be available on the AMCP website and also included in the Legislative-Regulatory Briefing Newsletter that is distributed to all AMCP members.

In addition, AMCP will host a webinar on February 24th from 3-4PM EST (note: new date and time) to review the proposed policy provisions and changes to Star Ratings that are applicable to AMCP members in the 2018 Draft Call Letter. This webinar is free for members and \$69 for non-members. To register, please visit AMCP's Calendar of Events at <http://www.amcp.org/calendar/>. A recording of the webinar will be available on the AMCP website the week of February 27th at <http://www.amcp.org/webinars/>.

CMS will release the 2018 Final Call Letter on April 3, 2017.

The following are areas of specific importance to AMCP that it is seeking feedback on from stakeholders:

- **Star Ratings & Display Measures:**
 - Medication Reconciliation Post Discharge (MRP) – CMS proposes to move the MRP measure from the display page to the 2018 Star Ratings. The measure would be weighted 1 for the 2018 Star Ratings and be increased to a weighting of 3 beginning in 2019.
 - AMCP is seeking feedback on whether the increase in weighting from 1 to 3 is warranted, or if the more traditional increase in weighting from 1 to 1.5 in subsequent years is more appropriate.
- **Efforts to Reduce Opioid Overutilization:** AMCP is seeking feedback on the following questions:
 - Are there concerns that there may be too many opioid measures currently on the display page and under development? Will these opioid measures potentially overlap and compete against one another?
 - OMS Opioid Overutilization Methodology – If a more significant revision to the methodology was implemented to target beneficiaries with more than 3 prescribers regardless of the number of opioid dispensing pharmacies, would the additional workload for Part D sponsors be manageable or effective?
 - Hard Formulary-Level Cumulative Opioid MED POS Safety Edits in CY 2018 – What has the Part D sponsor experience with these edits been to date, including pharmacist overrides/responses, if available, and setting the threshold at or above 200 mg MED?

More detailed information on each of key AMCP issues and other payment methodology and policy provisions contained in the Draft Call Letter is outlined in the summary below.

Changes in the Payment Methodology for Medicare Part D for CY 2018

Update of the RxHCC Model - page 37

- CMS proposes that plan liability for non-LIS beneficiaries in the coverage gap would be 56% for non-applicable (generic) drugs and 15% plan liability for applicable (brand) drugs in the coverage gap.

Encounter Data as a Diagnosis Source for 2017 - page 38

- CMS proposes to continue the transition to encounter data-based risk scores by maintaining the same blend as Payment Year (PY) 2017: CMS will blend two risk scores, weighting the risk score from RAPS and FFS by 75% and the risk score from EDS and FFS by 25%.
- For PACE organizations, CMS proposes to continue the same method of calculating risk scores that it has been using since PY 2015, which is to pool diagnoses from the following sources to calculate a single risk score (with no weighting): (1) encounter data; (2) RAPS; and (3) FFS claims.

Part D Risk Sharing - page 39

- CMS proposes that the risk percentages and payment adjustments for Part D risk sharing remain unchanged from CY 2017. Therefore, the risk percentages for the first and second thresholds would remain at 5% and 10% of the target amount, respectively. The payment adjustments for the first and second corridors would remain at 50% and 80%, respectively.

Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2018 - page 41

- As required by statute, CMS proposes the following Part D benefit parameters be updated in CY 2018 using the annual percentage increase (API) in average expenditures for Part D drugs per eligible beneficiary:

Table III-2. Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases			
	Annual percentage trend for 2017	Prior year revisions	Annual percentage increase for 2018
API: Applied to all parameters but (1) and (2)	3.94%	-2.62%	1.22%
July CPI (all items, U.S. city average): Applied to (1)	2.47%	-0.30%	2.17%
September CPI (all items, U.S. city average): Applied to (2)	2.41%	-0.20%	2.20%

Part D Benefit Parameters

	2017	2018 (proposed)
Standard Benefit		
Deductible	\$400	\$405
Initial Coverage Limit	\$3,700	\$3,750
Out-of-Pocket Threshold	\$4,950	\$5,000
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (3)	\$7,425.00	\$7,508.75
Estimated Total Covered Part D Spending for Applicable Beneficiaries (4)	\$8,071.16	\$8,417.60
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		

Generic/Preferred Multi-Source Drug	\$3.30	\$3.35
Other	\$8.25	\$8.35
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals (6)		
Deductible	\$0.00	\$0.00
Copayments for Institutionalized Beneficiaries (category code 3)	\$0.00	\$0.00
Copayments for Beneficiaries Receiving Home and Community-Based Services (5) (category code 3)	\$0.00	\$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL (category code 2)		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (6)	\$1.20	\$1.25
Other (6)	\$3.70	\$3.70
Above Out-of-Pocket Threshold	\$0.00	\$0.00
Over 100% FPL (category code 1)		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	\$3.30	\$3.35
Other	\$8.25	\$8.35
Above Out-of-Pocket Threshold	\$0.00	\$0.00
Full Subsidy-Non-FBDE Individuals		
Applied or eligible for QMB/SLMB/QI or SSI and income at or below 135% FPL and resources ≤ \$8,890 (individuals) or ≤ \$14,090 (couples) (7) (category code 1)		
Deductible	\$0.00	\$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	\$3.30	\$3.35
Other	\$8.25	\$8.35
Maximum Copayments above Out-of-Pocket Threshold	\$0.00	\$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below \$13,820 (individual) or \$27,600 (couples) (7) (category code 4)		
Deductible (6)	\$82.00	\$83.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	\$3.30	\$3.35
Other	\$8.25	\$8.35
Retiree Drug Subsidy Amounts		
Cost Threshold	\$400	\$405
Cost Limit	\$8,250	\$8,350

Reduced Coinsurance for Applicable Beneficiaries in the Coverage Gap - page 46

- CMS proposes that the beneficiary coinsurance under basic prescription drug coverage be reduced to 44% for non-applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit. After having applied the 50% manufacturer discount, the beneficiary coinsurance under basic prescription drug coverage would be reduced to 35% for applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit in 2018.
- To be eligible for reduced cost sharing, a Part D enrollee must have incurred gross covered drug costs above the initial coverage limit but true out-of-pocket costs (TrOOP) below the out-of-pocket threshold. Moreover,

Medicare beneficiaries enrolled in a qualified retiree prescription drug plan or those entitled to the low-income subsidy would not be eligible for this reduced cost sharing.

- CMS further specifies that the increased plan liability amounts do not count toward TrOOP. Part D sponsors must account for the reductions in cost sharing and increased plan liability when developing their Part D bids for payment year 2018.

Dispensing Fees and Vaccine Administration Fees for Applicable Drugs in the Coverage Gap - page 47

- As originally outlined in CY 2013, applicable beneficiaries will pay a portion of the dispensing fee (and vaccine administration fee, if any) that is commensurate with their coinsurance in the coverage gap, and the Part D sponsor will pay the remainder. In 2018, CMS proposes that applicable beneficiaries will pay 35% and plans will pay 65% of dispensing fees and vaccine administration fees for applicable drugs in the coverage gap.

Part D Calendar Year Employer Group Waiver Plans - page 48

- In light of rising specialty drug costs and their impact on EGWPs, CMS proposes to make prospective reinsurance payments to all CY EGWPs based on the average per member per month (PMPM) actual reinsurance amounts paid to CY EGWPs for 2015. The average PMPM reinsurance amount paid to CY EGWPs for 2015 reconciliation was \$32.00. This proposal will apply to all CY EGWPs offering Part D. CMS is not proposing to change the current policy of not paying reinsurance payments to non-calendar year EGWPs.

CY2018 Draft Call Letter

Enhancements to the 2018 Star Ratings and Beyond

New and Returning Measures for 2018 – page 79

- Medication Reconciliation Post Discharge (Part C) – page 79
 - CMS proposes to move the MRP measure from the display page to the 2018 Star Ratings.
 - For the future, CMS is considering rolling this indicator into a more comprehensive measure of care transitions with other indicators.
 - CMS proposes that the MRP measure be weighted 1 for the 2018 Star Ratings and increase to being weighted 3 starting with the 2019 Star Ratings. The increase in weighting is intended to reflect the MRP measure's role in assisting to improve a beneficiary's overall health status.
- Improving Bladder Control (Part C) – page 79
 - CMS proposes to move this measure to the 2018 Star Ratings with a weight of 1.

Changes to Measures for 2018 – page 80

- Improvement Measures (Part C & D) – page 80
 - CMS is implementing updates to the MS and PDP CAHPS survey to reflect the CAHPS 5.0 Health Plan Survey in 2017.
- SNP Care Management (Part C) and Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D) – page 81
 - No changes are being proposed to the specifications for these measures. However, CMS proposes to change the display of these measures for the 2018 Star Ratings from a percentage with one decimal point to an integer using standard rounding rules prior to applying the clustering methodology to calculate star assignments.
- Call Center – Foreign Language Interpreter and TTY Availability (Part C & D) – page 81
 - As discussed in the CY 2017 Call Letter, when testing interpreter availability, CMS will allow the interpreter an extra 60 seconds to answer an introductory question. Interpreters will be permitted up to eight minutes to answer the introductory question and up to seven minutes to answer each of the three accuracy questions that follow.

- MPF Price Accuracy (Part D) – page 81
 - As discussed in the CY 2016 and CY 2017 Call Letters, CMS plans to enhance this measure for the 2018 Star Ratings, using 2016 Medicare Plan Finder (MPF) pricing and PDE claims. These changes would 1) modify the PDEs to be included in this measure, and 2) account for the frequency and magnitude of difference between PDE and MPF prices when a contract’s PDE prices are higher than the MPF prices. These changes are intended to better depict the accuracy of a contract’s MPF posted prices.
 - CMS notes they are aware that while the MPF display is updated every two weeks, real time pricing at the point of sale can change as often as every day.
 - For consistency, these changes will also be made to the 2018 display measure, Plan Submitted Higher Prices for Display on MPF.
- Complaints about the Health Plan (Part C) and Complaints about the Drug Plan (Part D) – page 82
 - In the December 16, 2016 HPMS memo, Upcoming Complaints Tracking Module (CTM) Redesign, CMS announced that a redesigned CTM will be launched on March 18, 2017. Revisions will be made to the complaint categories and subcategories, including labels to indicate if they are excluded from the Star Ratings complaints measures.

Removal of Measures from Star Ratings – page 82

- High Risk Medication (Part D) – page 82
 - As indicated in the final 2017 Call Letter, the HRM measure will be moved to the display page for 2018 (based on 2016 data). CMS will continue to provide HRM measure reports to Part D sponsors through the Patient Safety Analysis website to identify outliers.

Adjusting Star Ratings for Audits and Enforcement Actions – page 82

- Beneficiary Access and Performance Problems – page 82
 - CMS proposes to revise the BAPP measure in the following manner:
 - Change the data timeframe to the time period from July of the measurement year to June of the following year. For example, the timeframe for the 2018 Star Ratings would be July 2016 through June 2017.
 - Employ a methodology for determining the CMP deduction for the revised BAPP measure that results in the same deduction for each contract held by a parent organization cited in a CMP notice.
 - The total deduction for a contract for CMPs be capped at 40 points, instead of 40 points per CMP.
 - Modify the BAPP measure cut points as follows:

• Table 2: BAPP Measure Cut Points

1 Star	2 Stars	3 Stars	4 Stars	5 Stars
0, 10 or 20	30 or 40	50 or 60	70 or 80	90 or 100

- CMS is considering one of two options and is seeking feedback on which option is preferred:
 - 1. Continue to include the revised measure in the Star Ratings with a weight of 1 and then increase to a weight of 1.5 for the 2019 Star Ratings
 - 2. Delay implementation of the revised measure until the 2019 Star Ratings.
 - Continue to include the current BAPP measure in the 2018 Star Ratings.
 - Include the revised BAPP measure on the 2018 display page.
 - Include the revised BAPP measure in the 2019 Star Ratings with a weight of 1 and then increase to a weight of 1.5 for the 2020 Star Ratings.
- CMS is also seeking comments on the various aspects of the proposed revised BAPP measure including: weight, data timeframe, revised methodology for the CMP deduction, retention of the CAM and sanction portions of the measure, and cut points.

Data Integrity – page 87

- CMS is continuing with pilot audits initiated in 2016. Audit criteria will be developed and finalized based upon findings from pilot audits.

2018 Star Ratings Program and the Categorical Adjustment Index (CAI) – page 87

- The application of the CAI for the 2017 Star Ratings resulted in a modest movement of the Star Ratings. Nineteen contracts saw their overall Star Rating increase by a half-star in their overall rating. Nine contracts moved from an overall rating of 3.5 to 4.0 after the CAI was applied to their unadjusted Star Rating. For MA-only and MA-PDs, seven contracts increased a half-star after the application of the Part C CAI value, and 16 MA-PD contracts increased a half-star in their Part D summary rating. The movement for stand-alone PDPs was bidirectional. Nine PDPs decreased a half-star and three increased a half-star after the application of the PDP-specific CAI values for the Part D summary rating.
- For the 2018 Star Ratings Program, CMS is proposing to continue the use of the CAI. The overall methodology would remain unchanged for 2018.
- The measures proposed for adjustment for the 2018 Star Ratings include the following three Part C measures for MA (MA-only, MA-PD) and 1876 contracts: Breast Cancer Screening, Osteoporosis Management in Women Who had a Fracture, and Diabetes Care – Blood Sugar Controlled. As done last year, in order to apply consistent adjustments across MA-PDs and PDPs, the Part D measures were selected by applying the selection criteria to MA-PDs and PDPs independently and, then, selecting measures that met the criteria for either delivery system. For the 2018 Star Ratings program, the two Part D measures: Medication Adherence for Hypertension (RAS antagonists) and Medication Therapy Management (MTM) Program Completion Rate for CMR are proposed for adjustment for MA-PDs and PDPs.
- Additional Response to Address Lack of an LIS Indicator for Enrollees in Puerto Rico – page 95
 - CMS proposes to continue to employ the methodology developed for the additional adjustment for Puerto Rico using the 2015 data from the American Community Survey and CY 2016 Medicare Enrollment data. CMS continues to explore alternative data sources for Puerto Rico to provide both resource and income information for the determination of the additional adjustment.
 - CMS proposes to continue to reduce the weights for the adherence measures to zero (0) for the summary and overall rating calculations and maintain the weight of three (3) for the adherence measures for the improvement measure calculations for contracts that solely serve the population of beneficiaries in Puerto Rico
- CMS notes that it is committed to building the foundation for a long-term solution that appropriately addresses the impact of socio-economic and disability status on Star Ratings. CMS will work with NCQA and PQA to review their measures to determine if any are sensitive to the composition of the enrollees in a plan and whether case-mix adjustment of individual measures would be appropriate.
- CMS seeks feedback on the continued use of the CAI and other suggestions for addressing this issue for CY 2018.

2018 CMS Display Measures – page 97

- CMS is proposing the following new or revised measures for the 2018 display page:
 - CAHPS measures (Part C & D) – page 97
 - In the 2017 Call Letter, CMS committed to shortening the 2017 MA CAHPS survey by removing some questions that are not used in current Star Ratings measures. The following items have been removed that were previously reported on the display page: Display items related to Reminders for appointments, Reminders for immunizations, Reminders for screening tests, Computer used during office visits, Computer use by provider helpful, Computer use made talking to provider easier, and Getting information from drug plan.
 - Pneumococcal Vaccination Status for Older Adults (Part C) – page 97
 - Recent stakeholder and public comment feedback indicates there is significant interest in finding alternative non-survey based methods to assess pneumococcal vaccination status and guideline adherence, such as claims, case management systems, medical records, registries and

- electronic health records. CMS is exploring potential non-survey based methods of collecting this information and welcomes feedback.
- In the meantime, the CAHPS measure has been reworded and will be included on the display page.
 - Hospitalizations for Potentially Preventable Complications (Part C) – page 98
 - CMS first included this measure on the 2017 display page, with plans to move it into the 2018 Star Ratings. Due to concerns from NCQA, the measure developer, CMS proposes to continue this as a display measure for 2018, and move it to the 2019 Star Ratings. Among the concerns raised by NCQA were a large number of outlier plans—those that performed much better or worse than other plans and for unknown reasons. Also, there was some interest in studying the potential bias that might occur when hospitals use observation stays instead of inpatient admissions.
 - Statin Therapy for Patients with Cardiovascular Disease (Part C) – [age 98
 - CMS proposes to maintain this measure on the 2018 display page, and plans to move it to the 2019 Star Ratings after gaining experiences with new treatment guidelines.
 - Asthma Measures (Part C) – page 99
 - Stakeholders expressed concerns that asthma and COPD might be difficult to distinguish among those age 65 and older. CMS and measure developers will consider the utility of prescription drug event and encounter data to solve these concerns before moving forward with implementing asthma measures; therefore Medication Management for People with Asthma will not be reported on the 2018 display page, nor on the 2018 Star Ratings.
 - Formulary Administration Analysis measure (Part D) – page 99
 - CMS proposes to adopt a new display measure using the results of the Formulary Administration Analysis (FAA) program by which CMS evaluates whether Part D sponsors are appropriately adjudicating Part D drug claims consistent with Part D requirements and sponsors' CMS-approved benefits. CMS is considering ways in which to expand TPMA and FAA monitoring to allow the inclusion in the Star Ratings as important beneficiary access measures. At the earliest, these measures may be proposed for the 2020 Star Ratings.
 - High Risk Medication (Part D) – page 99
 - As outlined above, the HRM measure will be moved to the 2018 display page.
 - The measure criteria and been revised by PQA to calculate the average dose for doxepin, reserpine, and digoxin. This change is proposed to be implemented for the 2018 display measure.
 - The HRM measure drug list was further revised to reflect the updated 2015 American Geriatrics Society (AGS) Beers Criteria. CMS proposes to implement the updated HRM drug list for the 2019 display measure (using 2017 data).
 - The HRM measure will be reconsidered for the Star Ratings again in the future upon additional analyses.
 - Drug-Drug Interactions (Part D) – page 100
 - The drug-drug pairs included in the DDI measure were reviewed by a PQA expert panel and resulted in a revised list of approved drug-drug interactions. CMS evaluated the revised drug list and overall the DDI rate decreased by 2.1% percentage points (1.9% and 2.1% percentage point decrease for MA-PD and PDP contracts, respectively).
 - CMS proposes to implement the revised DDI measure drug list for the 2019 display measure based on 2017 data.
 - Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes (Part D)– page 101
 - CMS proposes to remove this measure from the 2018 display page and replace it with the Antipsychotic Use in Persons with Dementia (APD) measure
 - Antipsychotic Use in Persons with Dementia (Part D) – page 101
 - CMS sent Part D sponsors 2016 APD measure reports on a monthly basis through the Patient Safety Analysis Website. There were three population breakouts:

- APD-COMM: Community-only residents (never a nursing home resident);
 - APD-STNH: Short-term nursing home residents (100 cumulative days or less in a nursing home based on the Long Term Care Minimum Data Set (MDS));
 - APD-LTNH: Long-term nursing home residents (greater than 100 cumulative days in a nursing home).
- CMS proposes to add only the overall APD measure to the 2018 display page (using 2016 data).
- CMS intends to improve the precision of the stratification rate calculations starting with the 2017 reports by meeting the numerator criteria while residing in the community or nursing home. CMS proposes to report only two population breakouts, Community-only and Long-term Nursing Home residents, for the 2019 display measures (using 2017 data) in addition to the overall APD rate. CMS will assess adding the APD measure to the Star Ratings in the future.
- Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D) – page 101
 - The three opioid measures that were included in the Patient Safety reports starting in 2016 were updated by PQA with several non-substantial changes:
 - Each rate will have a separate title
 - Morphine equivalent does will be changed to morphine milligram equivalents
 - The treatment period for Measures 1 and 3 must be 90 days or more
 - ICD-9 and ICD-10 codes will be changed to align with the American Medical Association (AMA) Physician Consortium for Performance Improvement (PCPI) cancer value set
 - All buprenorphine products indicated for medication-assisted treatment (MAT) will be excluded
 - Therefore, the revised opioid measures are proposed as:
 - Measure 1: Use of Opioids at High Dosage in Persons without Cancer (OHD): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine milligram equivalents (MME) for 90 consecutive days or longer.
 - Measure 2: Use of Opioids from Multiple Providers in Persons without Cancer (OMP): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.
 - Measure 3: Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine milligram equivalents (MME) for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.
 - CMS proposes to implement these changes beginning with the 2017 Patient Safety reports. CMS also proposes to add these measures to the 2019 display page (using 2017 data), but not to add these measures to the Star Ratings at this time.
- Statin Use in Persons with Diabetes (Part D) – page 102
 - CMS proposes the SUPD measure remain on the 2018 display page using 2016 data.
 - PQA has revised the measure to exclude beneficiaries with ESRD. CMS proposes to begin excluding beneficiaries based on ESRD indicator found in Medicare Enrollment Database beginning with the 2017 measurement year.
 - CMS proposes to add the SUPD measure to the 2019 Star Ratings using 2017 data.

Forecasting to 2019 and Beyond – page 103

- Patient Safety Report Frequency – page 103
 - Beginning with the 2017 reports, CMS proposes to generate the patient safety measures reports (and outlier notices) quarterly instead of monthly to reduce the variability due to data lags.
- Potential Changes to Existing Measures – page 103
 - Initiation and Engagement in AOD Treatment (Part C) – page 103
 - The IET measure assesses the percentage of adolescent and adult members with a new episode of alcohol or other drug dependence (AOD) who 1) initiated AOD treatment within 14 days of the diagnosis and 2) had two or more additional services for AOD treatment within 30 days of the initiation visit.
 - CMS is seeking feedback on including data on the use of Medication-Assisted Treatment (MAT) in the denominator and numerator components of the measure. These changes are being considered for data collection in 2018, which would lead to reporting of this measure on the display page in 2020.
 - Telehealth and Remote Access Technologies – page 104
 - CMS is seeking feedback on the appropriateness of including telehealth and/or remote access technology encounters, as allowed under the current statutory definition of Medicare covered telehealth services and/or as a provided by the MAO as a MA supplemental benefit, as eligible encounters in various Part C quality measures.
 - If such encounters were included, data from 2018 would reflect this change and could be included in 2020 display page.
 - Cross-Cutting Exclusions for Advanced Illness – page 104
 - CMS is seeking feedback on the clinical appropriateness and feasibility of excluding individuals with advanced illness from selected Part C measures as CMS recognizes that these measures may not be clinically appropriate for certain individuals with advanced illness and may overlook the quality issues that are specific to these patients. CMS is seeking feedback about whether specific illnesses and health care utilization (e.g., use of palliative care services) may warrant an exclusion, and to which measures the exclusion should be applied. However, CMS notes that they are concerned about any changes to measures that result in lessened incentives for providing high-quality care to such beneficiaries.
 - Care Coordination Measures (Part C) – page 104
 - CMS proposes to weight care coordination and transition measures as a 3 starting with the 2019 Star Ratings. This would include the CAHPS Care Coordination measure and Medication Reconciliation measure and additional measures in future years.
 - Center for Medicare and Medicaid Innovation Model Tests – page 105
 - CMS notes that some stakeholders have expressed concern regarding the potential for the improvements in quality resulting from the MA-VBID and the Part D Enhanced MTM Model (EMTM) test to adversely influence the Star Ratings of contracts ineligible to participate (or that include some PBPs ineligible to participate). CMS' goal is to not penalize participants or non-participants in either model. Therefore, CMS proposes the following:
 - For the MA-VBID Model test, CMS is considering the option of exclusion of VBID-participants' data when calculating the cut points for relevant measures.
 - For the EMTM test, MTM Program CMR Completion Rates will be calculated using available plan-reported data from non-EMTM participating plans. CMS plans to analyze if this approach significantly advantages or disadvantages EMTM participants and evaluate potential adjustments as necessary, including the establishment of different cut points for model participants or to case-mix adjust scores for the purpose of determining cut points.
- Temporary Removal of Measures from Star Ratings – page 105
 - Reducing the Risk of Falling (Part C) – page 105

- CMS is considering including dismissals and withdrawn appeals in this measure starting with the 2019 Star Ratings to align with the Part D appeals measure.
 - New PQA-endorsed Measures in Development for Future Testing/Consideration (Part D) – page 108
 - 1. Concurrent Use of Opioids and Benzodiazepines: The percentage of individuals 18 years and older with concurrent use of opioids and benzodiazepines.
 - 2. Adherence to Non-infused Disease Modifying Agents Used to Treat Multiple Sclerosis: The percentage of individuals 18 years and older who met the Proportion of Days Covered (PDC) threshold of 80% during the measurement period for disease-modifying agents treating multiple sclerosis.
- Measurement and Methodological Enhancements – page 109
 - CMS is seeking feedback on measures that should be transitioned to the display page starting with the 2019 Star Ratings due to measure scores being “topped out” or showing high performance across all contracts.
 - CMS is seeking feedback about the current evidence for age and appropriate methods for primary screening for breast cancer as it will be working with NCQA to review the Breast Cancer Screening HEDIS measure.
 - CMS is interested in developing new or enhanced measures of beneficiary access, especially with the industry-wide collection of data from all sponsors using CMS audit protocols for ODAG and CDAG. CMS is seeking feedback on the types of information that would be more important to Medicare beneficiaries when comparing their access to needed medical services and drugs.

Formulary Submissions

CY 2018 Formulary Submission Window – page 134

- The CY 2018 HPMS formulary submission window will open this year on May 15, 2017 and close at 11:59 PM PDT on June 5, 2017. CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 5, 2017 in order for the formulary to be considered for review.

CY 2018 Formulary Reference File – page 134

- CMS will release the first CY 2018 Formulary Reference File (FRF) in March 2017. The March FRF release will be used in the production of the Out-of-Pocket Cost (OOPC) model tool, scheduled to be released in April 2017, in order to assist plan sponsors in satisfying meaningful difference and MA TBC requirements prior to bid submission. Sponsors should note that the OOPC model released in April will not be modified to incorporate any subsequent FRF updates, as described below.
- In May 2017, CMS is planning to provide a subsequent release of the 2018 FRF prior to the June 5th formulary submission deadline. The May FRF will be released in mid to late May in order to allow for sufficient time to evaluate and add new Part D drugs that become available in the datasets.
- CMS will offer a summer formulary update window that will allow for the following formulary changes: 1) the addition of drugs that are new to the summer release of the FRF, and 2) the submission of negative changes on brand drugs, only if an equivalent generic or therapeutically similar drug is added to the summer FRF and corresponding formulary file within the same category and class, at the same tier or lower, and with no more restrictive utilization management than what was applied to the existing brand.

Changes to CY 2018 Formulary Submissions – page 135

- For CY 2018, CMS has proposed that the formulary file submission format will no longer contain a field for drug type label, and the options on the PBP will be streamlined to two options: brand and generic. This proposal is currently pending OMB approval.

United States Pharmacopeia (USP) Convention Medicare Model Guidelines – page 135

- Part D sponsors are expected to use version 7.0 of the USP Medicare Model Guidelines in their formulary development and submission process.

MTM Provisions, Tiers, & Access to Preferred Cost-Sharing Pharmacies

MTM Annual Eligibility Threshold – page 135

- The 2017 MTM program annual cost threshold is \$3,919. The 2018 MTM program annual cost threshold will be adjusted based on the annual percentage and finalized in the 2018 Call Letter.

Preferred and Non-Preferred Drugs – Page 137

- CMS reminds plans that when plans design their tiering exceptions criteria and adjudicate requests for tiering exceptions, CMS expects these sponsors to apply the correct definitions for preferred and non-preferred drugs. Pursuant to 42 C.F.R. §423.100, a preferred drug is “a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.” Sponsors should not base tiering exception eligibility on the tier label of the tier on which the alternative drug(s) are placed, but rather whether the tier has lower cost-sharing than the requested drug, thereby making it preferred. For example, if the plan sponsor's formulary includes Tier 2 – Generic (\$15 copay) and Tier 3 – Preferred Brand (\$45 copay), Tier 2 is preferred relative to Tier 3. In this example, Tier 2 is a mixed tier containing both brand and generic drugs. Outside of the allowable limitations established by CMS (e.g., the requested drug is on the specialty tier, there are no alternatives contained on any lower tier), plan sponsors should not restrict their consideration of a tiering exception request based on the tier label, and should not limit their consideration to a single lower tier if there are multiple lower tiers containing alternative drugs.

Approval of Tiering Exception Requests – page 137

- Chapter 18, §30.2.1.4 states that, “When a tiering exception is approved, the plan sponsor must provide coverage for the drug in the higher cost-sharing tier at the cost-sharing level that applies to the drug in the applicable lower cost-sharing tier.” CMS clarifies that, in situations where the requested drug has alternatives in multiple lower tiers and the plan sponsor has approved the request for a tiering exception, the plan must apply the cost-sharing for the lowest applicable cost-sharing tier that contains alternatives for the requested drug because, consistent with the manual provision, the lowest cost-sharing tier is the “applicable lower cost-sharing tier.” For example, if the requested drug is a generic drug on Tier 4 – Non-Preferred Drug, and there are alternative drugs on multiple lower tiers, e.g. both Tier 3 – Preferred Brand and Tier 2 –Generic that the plan or a higher level adjudicator has determined would be less effective or have adverse effects for the enrollee, the appropriate cost-sharing for the approved request would be the lowest tier, i.e., Tier 2.

Request for Information on Tiering Exceptions – page 138

- CMS is soliciting information, on a voluntary basis, related to tiering exceptions from plan sponsors, PBMs, and other interested stakeholders. Specifically, we are requesting the following aggregated at the PBP level:
 - At both the coverage determination and redetermination levels, information related to tiering exceptions request volume, approval/denial and appeal rates, compared to other types of cases;
 - At both the coverage determination and redetermination levels, data related to the reasons that tiering exception requests are approved or denied, for example:
 - Categorical denials, such as requests for drugs contained on the specialty tier, approved non-formulary drugs, or drugs for which there are no lower-cost alternatives on the plan's formulary
 - Medical necessity denials, such as requests where the plan sponsor is not able to obtain sufficient information to approve (a missing or incomplete supporting statement), or where the plan sponsor has determined the medical necessity criteria is not met
 - Data related to volume of requests for tiering exceptions to a \$0 copay tier, and rates/rationale for approval and denial;
 - Information about enrollee complaints related to tiering exceptions and ways CMS could improve beneficiary experiences with the tiering exceptions process; and
 - Specific areas of concern or confusion related to CMS policy for tiering exceptions encountered by plan sponsors, PBMs, beneficiaries, or other stakeholders, including areas identified through plan analysis of IRE overturns.

Specialty Tiers – page 144

- CMS proposes to maintain the \$670 threshold for CY 2018, but we will continue to investigate trends specialty pharmacy expenditures in order to shape future analyses involving the specialty tier.

Access to Preferred Cost-Sharing Pharmacies (PCSP) – page 139

- CMS proposes to continue to apply policies to address low access to PCSPs in CY 2018 and in succeeding plan years. The same outlier thresholders that have been in place since CY 2016 will be continued.

Urban	Pharmacy access within 2 miles of less than 40% of beneficiaries' residences
Suburban	Pharmacy access within 5 miles of less than 87% of beneficiaries' residences
Rural	Pharmacy access within 15 miles of less than 70% of beneficiaries' residences

Part D Benefit Parameters for Non-Defined Standard Plans

Table 20: Benefit Parameters for CY 2018 – page 143

	CY 2018 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC) ¹	
Enhanced Alternative Plan vs. Basic Plan	\$ 20
Enhanced Alternative Plan vs. Enhanced Alternative Plan	\$ 37
Maximum Copay: Pre-ICL and Additional Cost-Sharing Reductions in the Gap (3 or more tiers)	^{2,3} \$
Preferred Generic Tier	<\$20 ⁴
Generic Tier	\$20
Preferred Brand/Brand Tier	\$47
Non-Preferred Drug Tier	\$100
Non-Preferred Brand Tier	\$100
Injectable Tier	\$100
Select Care/Diabetic Tiers ⁵	\$11
Maximum Coinsurance: Pre-ICL (3 or more tiers)	^{2,3} \$
Preferred Generic Tier	25%
Generic Tier	25%
Preferred Brand/Brand Tier	25%
Non-Preferred Drug Tier	50%
Non-Preferred Brand Tier	50%
Injectable tier	33%
Select Care/Diabetic Tiers ⁵	15%
Maximum Coinsurance: Additional Cost-Sharing Reductions in the Gap for Applicable Beneficiaries (all tier designs) ⁶	³ \$
Preferred Generic Tier	24%
Generic Tier	24%
Preferred Brand/Brand Tier	55%
Non-Preferred Drug Tier	55%
Non-Preferred Brand Tier	55%

Injectable Tier	55%
Select Care/Diabetic Tiers ⁵	55%
Minimum Specialty Tier Eligibility	
1-month supply at in-network retail pharmacy	\$670

Improving Drug Utilization Review Controls in Medicare Part D

Changes to the OMS Opioid Overutilization Methodology – page 145

- CMS completed an analysis to assess the impact and validity of modifications made to the OMS opioid overutilization criteria in CY 2017. Based upon the analysis, CMS proposes modifying the OMS opioid overutilization in 2018 to be:
 - During the most recent 6 months,
 - Use of opioids with an average daily MED exceeding 90 mg for any duration; and
 - Received opioids from more than 3 prescribers and more than 3 pharmacies, OR from more than 4 prescribers regardless of the number of opioid dispensing pharmacies.
 - Beneficiaries with cancer diagnoses and beneficiaries in hospice are excluded.
 - Prescribers associated with the same single TIN will be counted as a single prescriber.
- The modifications are intended to more effectively identify opioid overuse that places a beneficiary at increased risk for an adverse event, better align with the CDC guidelines for opioid prescribing, and still be manageable for sponsors to use to trigger additional patient-specific utilization review and case management.
- CMS is also seeking feedback on a more significant revision to target beneficiaries with more than 3 prescribers regardless of the number of opioid dispensing pharmacies. Based on 2015 data, CMS estimates that over 114,000 beneficiaries would be identified and is seeking comment on whether this additional workload for Part D sponsors would be manageable or effective.

Proposed Changes to Part D Sponsors’ Internal Opioid Criteria for Retrospective Identification of Opioid Overutilization and Subsequent Case Management – page 148

- In light of the proposed changes to the OMS ‘Overutilization of Opioids’ criteria, CMS also proposes that 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 use of opioids with an average daily MED exceeding 90 mg for any duration during the measurement period as proposed for use by CMS in the OMS. Sponsors may use a lower MED threshold and may vary other criteria including the number of prescribers and pharmacies.

A Note about the Comprehensive Addiction and Recovery Act (CARA) of 2016 – page 148

- CMS notes that they are on track for implementation of Section 704 of CARA for plan year 2019. Section 704 permits Part D sponsors to establish drug management programs for at-risk beneficiaries under which Part D sponsors may limit such beneficiaries’ access to frequently abused drugs to certain prescribers and pharmacies.

CMS’ Expectation for Hard Formulary-Level Cumulative Opioid MED POS Safety Edits in CY 2018 – page 148

- CMS notes that as described in the final CY 2017 Call Letter, Part D sponsors were expected to implement hard and/or soft formulary-level safety edits based on a cumulative MED approach at POS at the pharmacy to prospectively prevent opioid overutilization, beginning in 2017. Also, all sponsors are expected to implement a hard edit, at a minimum in 2018, using reasonable controls to limit false positives. In addition to a hard edit, sponsors may also choose to continue to implement soft edits in 2018.
- PACE organizations are expected to comply with these expectations unless they do not adjudicate claims at POS.
- In implementing the hard cumulative MED safety edit, CMS expects sponsors’ P&T committees to develop the edit specifications based on the observed opioid overutilization in their Part D plans, and the reasonableness of the numbers of targeted beneficiaries for plan oversight. CMS recommends that the hard edit threshold be set no lower than 200 mg MED. CMS also expects sponsors to apply specifications to minimize false positives by accounting for known exceptions, such as hospice care, certain cancer diagnoses, reasonable overlapping

dispensing dates for prescription refills or new prescription orders for continuing fills, and high-dose opioid usage previously determined to be medically necessary such as through case management or the coverage determination and appeals process. CMS also expects sponsors to set criteria for the hard edit that are not so overly permissive that beneficiaries who are potentially at high risk for opioid overutilization would not be identified. CMS also recommends that the MED calculation be based on a consecutive high-MED days' method but rather an average MED method to better capture high opioid dose episodes. Sponsors may choose to include a prescriber count criterion in the edit specifications to enhance the safety aspect of the edit, but it is not required.

- CMS seeks feedback from sponsors on their experience with these edits to date, including pharmacist overrides/responses, if available, and setting the threshold at or above 200 mg MED.
- CMS notes that Part D sponsors will continue to submit information on their CY 2018 cumulative opioid MED POS edits using a template through HPMS. Additional information will be provided in an HPMS memo describing the submission process and due dates for submission.

Addressing Chronic Use of Benzodiazepine Sedative-Hypnotics in the Medicare Part D Population – page 149

- CMS notes there continues to be concerns regarding the risks and benefits of benzodiazepine use, especially in the elderly due to an increased risk of falling. CMS analyzed and tested the PQA measure, Use of Benzodiazepine Sedative-Hypnotic Medications in the Elderly (BSH), to assess the chronic use of these medications in the elderly enrolled in Part D and found that the average BSH measure rate across all Part D contracts was low (~1%) during 2014.
- CMS does not propose adding the measure to the Star Ratings or display measures at this time since the overall use of BSH medications in the elderly is not an absolute contraindication per the Beers Criteria and the BSH rates were low for most Part D contracts. CMS will continue to monitor BSH rates, and will consider outreach to outlier contracts in the future if necessary.
- CMS also strongly encourages Part D sponsors to evaluate their claims data and use drug utilization management tools to monitor beneficiaries' BSH use before it becomes chronic, and to assess prescriber rates to identify outliers for educational or administrative interventions

Clarification of Part D “Reference-Based Pricing” Policy – page 150

CMS clarifies that the Part D prohibition announced in the CY 2010 Call Letter that reference-based pricing cost-sharing designs would no longer be permitted in Medicare Part D beginning in 2010, applies only to the cost-sharing designs that require enrollees to pay a differential (i.e. penalty) based upon the difference between the negotiated price of the drug being dispensed and a lower-cost preferred reference drug. This policy does not otherwise prohibit reference-based payment arrangements negotiated between pharmacies and Part D sponsors (or their Pharmacy Benefit Managers) that establish the negotiated price.

Coordination of Benefits (COB) User Fee – page 150

The 2018 COB user fee will be collected at a monthly rate of \$0.116 for the first 9 months of the coverage year (for an annual rate of \$0.087 per enrollee per month) for a total user fee of \$1.05 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2018 bids.

Social Security Number Removal Initiative (SSNRI) – page 151

CMS reminds plans that beginning in 2018 the current Social Security based HICN will be replaced with a Medicare Beneficiary Identification number (MBI) as required under MACRA. MBIs will be assigned to all Medicare recipients, and cards will be mailed to beneficiaries beginning no earlier than April 2018. CMS notes they are aware that plans are preparing to modify applicable systems, processes, and relevant forms to account for use of either a HICN or MBI. CMS will issue additional policy and operational information for these business processes as well as for other business processes and systems in the future to assist plans with making these changes.

Part D Low Enrollment – page 151

Under 42 CFR §423.507(b)(1)(iii), CMS has the authority to non-renew Part D plans (at the benefit package level) that do not have sufficient number of enrollees to establish that they are viable plan options. CMS urges sponsors to voluntarily withdraw or consolidate any stand-alone plan with less than 1,000 enrollees. By April 2017, CMS will notify plans with less than 1,000 enrollees of available options for consolidation/withdrawal options.