Academy of Managed Care Pharmacy®
www.amcp.org

SUMMARY

AMCP Summary: ***Announcement of Calendar Year (CY) 2017 Medicare Advantage (MA) Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter***

Draft Released: February 19, 2016

Final Released: April 4, 2016

Effective Date: January 1, 2017

On April 4, 2016, the Centers for Medicare and Medicaid Services (CMS) released the 2017 Final Call Letter. AMCP is pleased to see that CMS acknowledged AMCP in the 2017 Final Call Letter and credits the important work that AMCP's Medication Therapy Management Advisory Group is doing to develop a framework to define drug therapy problems. AMCP will continue to collaborate with stakeholders in this area, such as PQA and the HIT Collaborative, to develop a standardized framework to allow for the shift towards outcomes-based measurements in Medicare Part D. AMCP will also work with CMS to share its work and recommendations for inclusion in future Call Letters.

AMCP is also pleased to see CMS alter its timeline for removing the high-risk medication (HRM) measure from the Star Ratings from 2017 to 2018 to allow sufficient time to develop additional measures that examine overuse and inappropriate use of prescription drugs. AMCP looks forward to continuing to work with CMS on this important issue and encourages CMS to be transparent with sponsors and provide advanced notice as future changes to HRM, or measures intended to replace HRM, are considered and to ensure that the perspective of geriatricians, managed care pharmacy, and other health care providers that are experts in this area are taken into consideration prior to finalization.

A side-by-side comparison of the key AMCP issues and other payment methodology and policy provisions contained in the Draft Call Letter versus the Final Call Letter is outlined in the following tables:

- Star Ratings & Display Measures
- Audits & Enforcement Provisions
- Seeking Ways to Improve Value and Efficiencies in Medicare Advantage
- MTM Provisions, CMS Enhanced Test Model for MTM, and Value Based Insurance Design
- Tiers & Specialty Medications
- Overutilization Policies for Opioids & APAP
- POS Pilot, Quantity Limits, & Mail Order
- Changes in the Payment Methodology for Medicare Part D for CY 2017

Star Ratings & Display Measures

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
• **Contracting Organizations with Ratings of Fewer Than Three Stars in Three Consecutive Years** - CMS proposed using a similar timeline as in CY 2016 for star-rating based terminations. CMS would issue contract non-renewal notices in February of each year, with an effective date of December 31st of the same year, to all contracts that meet the criteria for a star rating-based termination. In March, following the issuance of the non-renewal notices, beneficiaries enrolled in plans offered under the non-renewed contracts would receive notices advising them that they will need to choose a new plan during the next annual election period to continue their Part C and Part D plan enrollment without interruption during the following benefit year. CMS would not calculate or publish Star Ratings for non-renewed contracts during the year in which CMS issues the non-renewal notice.	• N/A	• Finalized as proposed
Changes to Measures for 2017 No new measures will be added to the 2017 Star Ratings. The 2017 Star Ratings methodology will remain the same as the 2016 Star Ratings methodology with the exception of the modifications to the following measures.		
• **Improvement Measures (Part C & D)** – CMS proposed that the methodology for incorporating measures into the calculation of the two improvement measures (one each for Part C and D) remain the same as in prior years, but be updated to account for measures with at least two years of data.	• N/A	• Finalized as proposed
• **Appeals Timeliness/Reviewing Appeals Decisions Measures (Part C) and Appeals Upheld Measure (Part D)** – Currently, these measures include cases that are reopened and decided by April 1 of the following contract year. In some instances, appeals filed in the 4th quarter of the year and then subsequently reopened may not be determined by the Independent Review Entity (IRE) by April 1. CMS proposed for the 2017 Star Ratings to modify these measure specifications so that if a reopening occurs and is decided prior to May 1, 2016, the reopened decision would be used. Reopenings decided on or after May 1, 2016 would not be reflected in these data, and the original decision result would be used.	• N/A	• Finalized as proposed
• **Contract Enrollment Data (Part C & D)** – CMS previously discussed changing the twelve month period from January through December to February through January of the relevant measurement period. After further review of the enrollment data, CMS has decided to NOT propose this change.	• N/A	• Finalized as proposed
• **Transition from ICD-9 to ICD-10 (Part C & D)** – During the transition period from ICD-9 to ICD-10, both codes will be used for NCQA HEDIS measures due to the look-back periods for some measures. The transition to ICD-10 is not relevant for PQA measures currently used in Star Ratings.	• N/A	• Finalized as proposed
• **Appeals Upheld Measure (Part D)** – CMS proposed to remove the exclusion for appeal cases for beneficiaries enrolled in hospice at any point during 2014 as CMS policy has not changed since 2014 in this regard and therefore the exclusion is no longer necessary.	• N/A	• Finalized as proposed
• **Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D)** – CMS proposed adding a detailed file during each HPMS plan preview	• N/A	• Finalized as proposed

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
period to list each contract's underlying denominator, numerator, and Data Validation score since exclusions are applied to the plan-reported MTM data. CMS stated that it continues to look forward to the development and endorsement of outcomes-based MTM measures as potential companion measures to the current MTM Star Ratings.		
• **Medication Adherence for Hypertension (RAS Antagonists) (Part D Star Rating)** – CMS proposes that this measure will exclude from the denominator those patients with one or more claims for sacubitril/valsartan due to PQA specification changes beginning with the 2017 Star Ratings.	• N/A	• Finalized as proposed
Removal of Measures from Star Ratings		
• **Improving Bladder Control (Part C)** – CMS proposed that this measure be reported on the 2017 display page due to revisions in the questions used to assess it.	• N/A	• Finalized as proposed, with the addition that the measure will remain on the display page for both 2017 and 2018. CMS will request further input on this measure in the 2018 Draft Call Letter and looks to NCQA for leading the effort in revising this measure.
• **High Risk Medication (Part D)** – CMS proposed the HRM measure be removed from the Star Ratings and moved to the display page for 2017 based on a recommendation from the American Geriatrics Society (AGS) that the Beers Criteria not be applied in a punitive manner and the recognition that identification as a HRM is not a contradiction to use, but rather an encouragement to avoid use without first considering the risks and benefits to the individual. CMS would continue to provide HRM measure reports to Part D sponsors on a monthly basis through the Patient Safety Analysis website and continue to identify outliers. CMS may consider the HRM measure for Star Ratings again in the future and recommended that measure developers further review the HRM measure to understand the association between dual eligible/low income status and HRM use.	• AMCP appreciated that CMS recognizes the AGS' recommendation that the Beers Criteria not be applied in a punitive manner and the recognition that identification as a HRM is not a contradiction to use, but rather an encouragement to avoid use without first considering the clinical risks and benefits to the individual patient. However, AMCP cautioned CMS to carefully consider the timing of when this change should be made and recommended that CMS revise the timeline for removing the HRM measure from the Star Ratings from 2017 to 2018, to allow sufficient time to develop additional measures that examine overuse and inappropriate use of prescription drugs. Furthermore, AMCP encouraged CMS to be transparent with sponsors and provide advanced notice as future changes to HRM, or measures	• CMS delayed the timeline for removing the HRM measure from the Star Ratings from 2017 to 2018 due to the measurement period concerns raised, specifically since the change was being made after the measurement period in which efforts were invested by plan sponsors. The HRM measure will remain in the 2017 Star Ratings and will be moved to the display page in 2018. • CMS will continue to provide HRM measure reports to Part D sponsors on a monthly basis through the Patient Safety Analysis website, and will continue to identify outliers. • CMS will reconsider the HRM measure for the Star Ratings again in the future once analyses and specification changes, if any, are completed by PQA. CMS states that any changes will be proposed or implemented

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
	intended to replace HRM, are considered and to ensure that the perspective of geriatricians, managed care pharmacy, and other health care providers that are experts in this area are taken into consideration prior to finalization.	with sufficient lead time.
Data Integrity		
• CMS proposed that program audits will soon include review of Part D sponsors' MTM programs to determine bias outside of the Data Validation results such as attempts to restrict eligibility from approved MTM programs, encouraging beneficiary opt-out of MTM programs within the first 60 days, or comprehensive medication reviews (CMRs) that do not meet CMS' definition per guidance. The increased rigor in validation of MTM-related Star Ratings data is to ensure that CMS does not reward contracts with falsely high ratings. AMCP seeks input from members and other stakeholders to provide feedback on the scope of these audits. CMS proposed that audit criteria be developed and finalized based upon findings from pilot audits.	• AMCP believes the proposed audits will provide data to help the industry understand how different practice models with positive results can be replicated across Part D sponsors. AMCP was pleased to see CMS perform pilot audits prior to finalizing audit criteria. AMCP encouraged CMS to be transparent with sponsors during the pilot phase and provide timely information to sponsors on draft audit criteria	• Finalized as proposed
Impact of Socio-economic and Disability Status on Star Ratings		
• CMS research to date has provided scientific evidence that there is a within-contract socio-economic and disability status effect for a subset of the Star Ratings measures. After exploring two options for interim analytical adjustments to address this, CMS proposed to move forward with the proposed interim analytical adjustment of the Categorical Adjustment Index (CAI) beginning with the 2017 Star Ratings. The CAI approximates the effect of case-mix adjustment of contract performance scores for DE/LIS and disabled status. MA contracts would have up to three adjustments – one for the Overall Star Rating and one for each of the Summary Ratings (Part C and Part D). Part D plans would have one adjustment for the Part D Summary Rating. • CMS recognized differences in legislative and regulatory requirements that result in unique challenges in Puerto Rico, and therefore, proposed moving forward and implementing the interim estimates for the LIS indicator instead of waiting for the availability of a different data source.	• N/A	• Finalized as proposed, with the clarification that for Puerto Rico, the interim estimates for the LIS indicator will be modeled based on the ten (10) states with the highest level of poverty for the 2017 Star Ratings.
2017 CMS Display Measures		
• **Timely Receipt of Case Files for Appeals (Part D) & Timely Effectuation of Appeals (Part D**) – CMS proposed to change the data time frame from the first six months of the current year to Jan 1 – Dec 31 of the previous year. This change would allow the appeal display measures to match the same timeframe used for the Part D Appeal Star Ratings measures.	• N/A	• Finalized as proposed

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
• **Medication Reconciliation Post (MRP) Discharge (Part C)** – CMS proposed to expand MRP to all MA plans and members 18 years and older and include it the display page for 2017 as it believes expansion of the MRP measure is an important step to measure the quality of care coordination post-discharge for MA beneficiaries as well as ensuring patient safety. CMS planned on including the expanded MRP measure in the 2018 Star Ratings.	• AMCP appreciated that CMS intended to expand the MRP measure, but remained concerned that this may be duplicative with other post-discharge measures in place for areas outside of pharmacy and the patient confusion, alert fatigue, and disruption that may result. AMCP encouraged CMS to develop mechanisms to decrease redundancy and overlap, and encourage team based care.	• Finalized as proposed
• **Hospitalization for Potentially Preventable Complications (Part C**) – CMS proposed to include this measure on the 2017 display page and planned to include it in the 2018 Star Ratings, as it believes this is an important indicator of care coordination as it assesses the rate of hospitalization for complications of chronic and acute ambulatory care-sensitive conditions.	• N/A	• Finalized as proposed
• **Statin Therapy for Patients with Cardiovascular Disease (Part C)** – CMS proposed to include a new measure on the 2017 and 2018 display page for the percentage of males 21 to 75 years of age and females 40 to 75 years of age who were identified as having clinical atherosclerotic cardiovascular disease and were dispensed at least one high or moderate-intensity statin medication during the measurement year. CMS planned to include it in the 2019 Star Ratings after gaining experience with the new treatment guidelines and metric.	• N/A	• Finalized as proposed
• **Asthma Measures (Part C) –** CMS proposed to include two expanded asthma measures on the 2017, and possibly the 2018, display page. CMS will consider these for inclusion in future Star Ratings. o The percentage of members 5 to 85 years of age identified as having persistent asthma and dispensed appropriate medications that they remained on during the treatment period. o Asthma Medication Ratio which is the percentage of members identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year.	• N/A	• Finalized as proposed, with confirmation that it will appear on the 2017 and 2018 display page and be considered for inclusion in future Star Ratings
• **Statin Use in Persons with Diabetes (SUPD) (Part D)** – CMS proposed to include a new measure on the 2017 and 2018 display page for the percentage of patients between 40 and 75 years old who received at least two diabetes medication fills and also received a statin medication during the measurement period. Beneficiaries in hospice care would be excluded from the denominator for the entire year. Beneficiaries taking PCSK-9 inhibitors will NOT be excluded from the denominator. CMS planned include it in the 2019 Star Ratings after gaining experience with the new treatment guidelines and metric.	• N/A	• Finalized as proposed
New Measures The following measures are under consideration for the 2018 Star Ratings and will be reported as 2017 display measures.		

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
• **Care Coordination Measures (Part C)** – CMS is working to identify potential new care coordination measures and is utilizing experts to conduct targeted research, extensive literature reviews, data analysis, and to engage in discussions with expert panels and high performing plans. NCQA, using administrative and medical record data, will begin testing the following proposed measures using 2015 data: primary care provider (PCP) notification of inpatient admissions, summary of care record in PCP chart, follow-up with PCP/specialist following hospital discharge or emergency department visit, and in the ambulatory setting whether there is a comprehensive assessment performed and documented by the PCP/specialist and whether there is a specialist visit summary in the PCP chart.	• N/A	• Finalized as proposed. CMS will provide more information about this work as it is available.
• **Depression Measures (Part C)** – CMS is considering a new measure to assess the percentage of individuals age 12 and older with depression and an elevated PHQ-9 score (greater than 9) who achieve a PHQ-9 score of less than 5 at six months or have a 50% reduction in their PHQ-9 score. This measure also uses a new data collection methodology for HEDIS, relying on data coming from electronic clinical data systems (e.g., EHRs, clinical registries, case management records). If approved, the new measure would be published in HEDIS 2017.	• N/A	• Finalized as proposed
• **Appropriate Pain Management (Part C)** – NCQA is exploring opportunities to develop a new measure(s) focusing on appropriate pain management. The intent is to assess the quality of pain management and treatment. There is no definite timeline established for the development of this measure.	• N/A	• Finalized as proposed
• **Use of Opioids from Multiple Providers or at High Dosage in Persons without Cancer (Part D)** – CMS proposes developing three new safety opioid overutilization measure reports in to provide to Part D sponsors on a monthly basis through the Patient Safety Analysis website: o The proportion (XX out of 1,000) of individuals without cancer or hospice receiving prescriptions for opioids with a daily dosage greater than 120mg morphine equivalent dose (MED) for 90 consecutive days. o The proportion (XX out of 1,000) of individuals without cancer or hospice receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies. o The proportion (XX out of 1,000) of individuals without cancer or hospice receiving prescriptions for opioids with a daily dosage greater than 120mg MED for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies. • CMS will consider adding these measures to the 2019 display page after gaining at least one year of experience with the measures and pending new guidelines. • CMS does not recommend including these measures in the Star Ratings at this time because of lack of consensus on clinical guidelines for opioid prescribing and pending additional data.	• AMCP remains concerned that the proposed opioid measures require clarification prior to implementation. AMCP urged CMS to clarify the timeframe for Measure 2 (Multiple Prescribers and Multiple Pharmacies) and Measure 3 (Multi-Provider, High Dosage). Depending on the timeframe, it may be reasonable that a patient receives prescriptions for opioids from four or more prescribers and four or more pharmacies. Therefore, defining a timeframe to accompany the measures is necessary to alleviate both false positives and false negatives. Furthermore, AMCP urged CMS to consider proactive means of identifying at-risk beneficiaries such as expanding lock-in programs to Medicare Part D beneficiaries	• Finalized as proposed

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
	and allowing health plans to access state PDMP data.	
• **Antipsychotic Use in Persons with Dementia (APD) (Part D)** – CMS proposes the APD measure, with breakout rates for community-only residents, short-term nursing home residents, and long-term nursing home stay residents, be included in the 2018 display page and replace the Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes display measure. CMS does not recommend including this measure in the Star Ratings at this time pending additional research.	• N/A	• Finalized as proposed
Changes to Existing Star Ratings and Display Measures and Potential Future Changes		
• **MPF Price Accuracy (Part D Star Rating)** – CMS proposes several changes to this measure for the 2018 Star Ratings using 2016 PDE and MPF data: o Expansion of claims from solely 30-day supplies to include 28-34, 60-62, and 90-93 day supplies. o Use of the PDE-reported Pharmacy Service Type code in conjunction with the MPF Pharmacy Cost data to identify retail claims. o Changes to methodology by which price accuracy is calculated to also factor in how often PDE costs exceeded MPF costs.	• N/A	• Finalized as proposed
• **Drug-Drug Interactions (DDI) (Part D Display)** – CMS anticipates extensive changes to the DDI measure based upon recommendations from an expert panel that are currently being tested by PQA. CMS will continue to monitor any updates from PQA and propose changes to this measure in the future.	• N/A	• Finalized as proposed
• **Center for Medicare and Medicaid Innovation Model Tests** – For the MA-VBID Model test, CMS is considering the exclusion of some of the model-participants' data when calculating measure-level cut points. CMS is proposing that the Part D plans participating in the Part D Enhanced MTM Model Test will be waived from MTM requirements under Section 1860D-4(c)(2) and 42 CFR 423.153(d) and the Part D reporting requirements for MTM, but will still be required to comply with current requirements and reporting data for the remaining plans under each Part D contract. CMS will closely monitor performance trends of participating plans once the model tests are implemented and determine if any changes are warranted.	• N/A	• CMMI test models will begin in January 2017 and will not affect Star Ratings until 2019. CMS will provide additional details about the approach for model participants' Star Ratings in a future Call Letter.
Measurement and Methodological Enhancements		
• CMS is considering whether to allow the interpreter an extra 60 seconds to address an introductory question that is asked prior to three specific plan benefit questions. Any changes made to the 2017 call center monitoring methodology would be announced in a fall 2016 HPMS memo.	• N/A	• Beginning in 2017, CMS will allow the interpreter an extra 60 seconds to address an introductory question that is asked prior to three specific plan benefit questions. This will affect the 2018 Star Ratings. Additional details will be provided in the fall 2016 HPMS memo.

Audits & Enforcement Provisions

CMS Proposal in 2017 Draft Call Letter	2017 Final Call Letter
• **Medicare Parts C & D Program Audits –** In response to stakeholder feedback, beginning with the 2017 audit protocols, CMS proposed to release the following year's protocols by the end of July, instead of mid-to-late fall. Therefore, the 2017 protocols would be released in July of 2016.	• CMS acknowledges that in its proposal it forgot to account for the time it takes to get changes approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) and the mandatory 60-day and then subsequent 30-day comment periods. CMS will work on finalizing its proposal through the formal OMB process and will seek additional stakeholder feedback during that time. • For audit protocols being piloted for MTM and Provider Network Adequacy (PNA), CMS is extending the pilot of these protocols into 2017 to allow time to gather feedback and determine if revisions are needed to the pilot audit protocols.
• **Civil Money Penalty (CMP) Calculation Methodology** – CMS plans to release a memo describing their interpretation of the applicable rules in a CMP Methodology by 2017, but will provide an opportunity for industry to comment before finalizing. This CMP methodology may be modified and republished on an as needed basis.	• Finalized as proposed
• C**ompliance and Enforcement Actions Related to Part D Auto-Forwards** – CMS notified Part D plan sponsors that, in 2017, the Agency will continue to increase the level and severity of the compliance and enforcement actions imposed on plans that substantially fail to comply with adjudication requirements for coverage determinations and redeterminations.	• Finalized as proposed, with clarification that the thresholds used in determining whether a sponsor is considered an outlier will be as follows: o CMS will use data to determine which plan sponsors are outliers with respect to untimely decisions and the corresponding rate at which cases are auto-forwarded to the Part D IRE per 10,000 enrollees. This outlier threshold will be established each year and will be based on a quarterly auto-forward rate per 10,000 enrollees. This outlier threshold will be in alignment with the Star Ratings auto-forward measure 2-star cut-point (for the 2016 Star Ratings this annual cut-point was 38.5 - 66.8).
• **Enforcement Actions Related to One Third Financial Audit Findings** – CMS notified Part C & D plan sponsors that, starting with audits conducted in 2017 (based on CY 2015), the Agency will begin to consider the findings of noncompliance from the financial audits for potential enforcement actions.	• Finalized as proposed, with the clarification that further information about what criteria will be used in determining potential enforcement actions will be shared in advance with the industry.

Seeking Ways to Improve Value and Efficiencies in Medicare Advantage

CMS Proposal in 2017 Draft Call Letter	2017 Final Call Letter
• **Cost Sharing/Bundling with Facility –** CMS is concerned about the transparency of costs sharing for MA beneficiaries. CMS noted the agency is aware that in some cases an enrollee may receive a service in a facility setting that includes an additional facility fee that does not apply when the service is furnished in a physician's office. While MA plans may have higher copays based on place of service, CMS indicated that they should, to the extent possible, include the enrollee's entire cost sharing responsibility in a single copay. Accordingly, in situations where there is a difference in cost sharing based on place of service, those fees are to be combined (bundled) into the cost sharing amount for that particular place of service and clearly reflected as a total copayment in appropriate materials distributed to beneficiaries.	• CMS clarifies that its expectation is that an MA enrollee will see the actual and complete cost sharing for a particular service fully and clearly disclosed in the members' Evidence of Coverage (EOC) document, in Medicare Plan Finder, and in plan materials. To avoid the enrollee confusion caused by charging multiple cost share amount for a single service CMS further clarifies that they expect MAOs to charge a single cost sharing amount to enrollees that combines all cost sharing associated with a particular service.
• **Interoperability-MA Plans and Contracted Providers –** CMS is exploring how best to encourage the adoption of technology that supports interoperability between MA plans and their contracted providers, and the need for rulemaking to require such adoption. CMS sought comments from the industry regarding their experience with these activities, including barriers to successful adoption.	• CMS will take the comments received into consideration as it considers future policy-making, especially with respect to providers participating in alternative payment models. In addition, CMS will continue to gain insight from the industry and other stakeholders, into the complexities of adopting technology that supports interoperability.
• **Alternate Payment Models (APMs)** – In the CY 2016 Call Letter, CMS indicated that it would reach out to MAOs to gain a better understanding of their use of provider incentives and value based contracting for physician services. Subsequently, CMS had conversations with a number of MAOs concerning their use of alterative payment models (APMs). As a result of the high level of interest in the use of APMs and the long-term HHS payment goals, CMS has added APM questions to the Part C reporting requirements. Specifically, CMS will ask MAOs to report on the proportion of payments made to providers based on the HHS developed four categories of value-based payment: fee-for-service with no link to quality; fee-for-service with a link to quality; alternative payment models built on fee-for-service architecture; and population-based payment. In order to maintain consistency with HHS goals of increasing the proportion of payments made based on quality and value, CMS will continue to support MAOs' efforts to improve cost efficiency, reduce costs, and improve health outcomes through the use of APMs. CMS sought comments from the industry regarding challenges and concerns associated with the use of APMs in Medicare Advantage.	• CMS states some MAOs asked that CMS further clarify and define the HHS categories of value based payment. CMS refers plans to the LAN APM Definitional Framework White Paper at https://hcp-lan.org/workproducts/apm-whitepaper.pdf for more information on the categories.
• **Improving Clinical Decision-Making for Certain Part D Coverage Determinations –** CMS is considering rulemaking that would allow extensions to Part D adjudication timeframes in certain limited circumstances (*e.g.,* situations where the timeframe is impacted by a weekend or holiday; requests for drugs that require prior authorization (PA) or step therapy (ST); and cases where the plan does not have all necessary information from the prescriber required to make a clinically appropriate decision based on approved criteria). Extensions would not be permitted for exception requests.	• CMS does not intend to move forward with any proposed regulatory changes for extensions in Part D at this time as CMS agrees with the commenters who noted that written notice of the extension—an important beneficiary protection—would not be feasible, and that the limitations suggested could be confusing for plans, beneficiaries and prescribers, and difficult for plans to implement and oversee effectively. CMS also agrees with the numerous commenters who expressed concerns about making broader changes to adjudication timeframes, including a more expansive extension opportunity, given the more immediate need for access to drug therapy and that fact that coverage must be approved before the

CMS Proposal in 2017 Draft Call Letter	2017 Final Call Letter
	enrollee can access the drug. • CMS will continue to explore how it might assist plans and PBMs in providing fully informed coverage determinations, limiting unnecessary denials, and avoiding delays that could potentially cause beneficiary harm. After consideration of the comments received on the draft Call Letter, CMS intends to direct its efforts on reducing the volume of coverage determination requests that are initially incomplete, including exploring how increased use of electronic health records and other technology could make the information needed from prescribers more accessible outside of business hours; encouraging the increased use of e-prescribing and e-prior authorization to increase dissemination of plan formularies to prescribers at the point of care; and leveraging MA-PD plan contracting arrangements with network providers who are prescribing Part D drugs. • CMS is currently developing additional subregulatory guidance to help ensure that Part D plan sponsors are consistently conducting appropriate outreach to prescribers to obtain missing information and make informed decisions within the existing Part D timeframes.
• **Access to Preferred Cost-Sharing Pharmacies** – In response to some plans offering very low access to preferred cost-sharing pharmacies (PCSPs), in the CY 2016 Call Letter, CMS announced that it would 1) post information about 2016 PCSP access levels on the CMS website and 2) require plans who were outliers with respect to access to PCSPs to disclose that their plan's PCSP network offered lower access than other plans. This year, CMS reported increased PCSP access for 2016. CMS proposed to continue its PCSP policy as announced in the 2016 Call Letter and implemented for the 2016 plan year. Plans that provide PCSP access within 2 miles of less than 40% of beneficiaries' residences in urban areas, within 5 miles of less than 87% of beneficiaries' residences in suburban areas, and within 15 miles of less than 70% of beneficiaries' residences in rural areas will be identified as outliers in 2017.	• Finalized as proposed

MTM Provisions, CMS Enhanced Test Model for MTM, and Value Based Insurance Design

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
• **Annual MTM Eligibility Cost Threshold –** CMS proposed that the 2017 MTM program annual cost threshold will be adjusted based on the annual percentage and finalized in the 2017 Call Letter.	• N/A	• The 2016 MTM program annual cost threshold is $3,507. The 2017 MTM program annual cost threshold is updated for 2017 using the annual percentage increase of 11.75%, as specified in the Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Therefore, the 2017 MTM program annual cost threshold is $3,919.
• **Annual MTM Submission and Approval Process –** Beginning with the CY 2017 submissions, CMS proposed to implement a modified annual MTM program review process and add attestations to the HPMS submission module as follows: o All Part D sponsors would continue to submit an MTM program description through HPMS each year. Sponsors would continue to submit change requests throughout the year. o Attestations of the Part D sponsor's compliance with Part D MTM program requirements would be added to the MTM submission module in HPMS. o Sponsors must attest to meeting the MTM program requirements during the annual submission. Sponsors must re-attest when they submit change requests. The user completing the MTM submission and attestations in HPMS must have the authority to attest on behalf of the organization. o A subset of MTM program submissions would be comprehensively reviewed: ▪ Any new contracts; ▪ Any contracts whose MTM submission failed initial review the prior year; ▪ Any contracts that failed reporting requirements data validation or audit for MTM (when implemented); ▪ Any contracts that scored less than 3 stars on the MTM comprehensive medication review completion rate measure; ▪ A random sample of other program submissions. • CMS would continue to monitor beneficiary complaints, validation results of plan-reported MTM data, and CMS program audits of MTM programs.	• N/A	• Finalized as proposed, with the following clarification: o The user completing the MTM submission and attestations in HPMS must have the authority to attest on behalf of the organization. CMS clarifies this means the Chief Executive Officer (CEO), Chief Operating Officer (COO), or the Chief Financial Officer (CFO).
• **Submission Requirements for Enhanced MTM Model Participants –** CMS proposed to waive the current MTM requirements for the PDPs approved to participate in the Enhanced MTM Model and data	• N/A	• Finalized as proposed

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
on participating PDPs must not be reported per the Part D Reporting Requirements under the current MTM program. This MTM data would instead be reported in accordance with model terms and conditions. CMS would notify the subset of plans that are NOT subject to current MTM requirements. Plan sponsors with contracts that include PDPs that are not eligible to participate in the model must ensure that those non-participating plans comply with all standard MTM program requirements, including the submission of MTM program details in HPMS. More information will be provided in the annual MTM program guidance and submission instruction memo for CY 2017.		
• **Part D Reporting Requirements for MTM –** For monitoring purposes, Part D sponsors are responsible for reporting several data elements to CMS related to their MTM program per the Part D Reporting Requirements. CMS proposed that element X, "Topics discussed with the beneficiary during the comprehensive medication review (CMR), including the medication or care issue to be resolved or behavior to be encouraged", be suspended for the 2016 Part D Reporting Requirements until a more standardized set of data can be collected. CMS noted that the industry, including PQA and the Academy of Managed Care Pharmacy (AMCP), is working on a framework to define drug therapy problems (DTPs). Sponsors should begin to develop the capacity to collect and report drug therapy problems using a standard framework and common terminology. CMS plans to propose new data elements for the Part D Reporting Requirements through the Paperwork Reduction Act (PRA) process as early as 2017 to capture drug therapy problems at the beneficiary-level using standard categories and definitions.	• AMCP believes that the consistent use of structured universal codes is critical to the expansion of documentation of MTM services and supports the use and implementation of SNOMED CT codes for the exchange of information. SNOMED CT documentation for MTM services will allow the pharmacist to document the clinical care that is provided through encounter-based coding and intervention-based coding. Encounter-based coding elements for MTM services include reasons or indications for the MTM visits and a description of the services that were provided (e.g., referral to MTM service, complications with medication therapy, comprehensive medication therapy review, targeted medication therapy review, medication-related action plan, pharmacist consultation with health care provider, patient education). Intervention-based coding allows the pharmacist to document drug therapy problems identified during the medication regiment assessment, as well as provide the necessary SNOMED CT codes to document the patient's care plan or medication action plan. Use of standardized SNOMED CT codes, coupled with a framework for defining drug therapy	• Finalized as proposed

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
	problems, will allow for the shift towards outcomes-based measures versus the traditional process-based measures that are used today in Part D.	

Tiers & Specialty Medications

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
• **Tier Labeling and Composition –** After receiving feedback from a number of plan sponsors, CMS proposed a non-preferred drug tier option that would allow for a drug mix regardless of brand/generic status. The proposal was pending approval by the Office of Management and Budget, Office of Information and Regulatory Affairs. If approved, sponsors would have the option of selecting a non-preferred drug tier or non-preferred brand tier but not both. CMS noted that, although sponsors using a non-preferred drug tier have the option of choosing either copay or coinsurance cost sharing with the same thresholds as the non-preferred brand tier, CMS encouraged Part D sponsors to consider using a coinsurance for the non-preferred drug tier instead of a copay. Until further notice, CMS will conduct an outlier test for those Part D sponsors who choose a copay for the non-preferred drug tier, to determine if beneficiaries will receive a benefit for the majority of drugs on this tier at the proposed copay.	• AMCP believes the creation of a non-preferred drug tier is a step in the right direction to encourage innovation in plan design. AMCP encourages CMS to be transparent and share results from outlier tests to help determine the benefit of the new tier to patients, including the benefits of coinsurance over copay.	• Finalized as proposed with the following clarifications: o After reviewing comments that suggest beneficiaries tend to prefer copay structures, CMS will allow Part D sponsors the flexibility to determine what cost-sharing structure is most appropriate for their benefit design. CMS expects, however, that sponsors evaluate, and be prepared to demonstrate if necessary, that the cost-sharing structure chosen provides a value for beneficiaries. CMS will continue to evaluate the type and level of cost-sharing that is most appropriate for this tier. o The existing tiering exception guidance is applicable to the new tiering option.
• **Benefit Review –** In 2017, the minimum monthly cost-sharing out-of-pocket costs (OOPC) difference between basic and enhanced Part D plan offerings will be $23 and the minimum monthly cost-sharing OOPC difference between enhanced Part D plan offerings will be $34. In the 2016 Call Letter, CMS proposed instituting a TBC measure for PDPs, similar to what has been in place for MAOs. However, for CY 2017, CMS proposed to not implement an OOPC or market basket approach to set thresholds for increases in cost-sharing and premiums whereby CMS would deny Part D plan bids with significant increases. Instead, CMS would calculate and publish the Part D TBC to support transparency related to the out-of-pocket beneficiary costs year over year.	• N/A	• Finalized as proposed
• **Specialty Tiers -** Per 42 CFR 423.578 (a)(7), if a Part D plan sponsor maintains a formulary tier (the specialty tier) in which it places high cost products, the sponsor may design its exception process so that very high cost or unique drugs 13 are not eligible for a tiering exception. Only Part D drugs with sponsor-negotiated prices that exceed an established dollar-per-month threshold are eligible for specialty tier placement. The current cost threshold of $600 was established in CY 2008. CMS continues to evaluate	• AMCP believes this change will probably have a negligible impact as the number of specialty medications that fall between the $600/month and $670/month thresholds is limited. However, AMCP will monitor the	• Finalized as proposed, with the following additions: o To assist in future policy decisions, CMS will also conduct a series of analyses to investigate 1) whether

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
the specialty tier eligibility cost threshold and until this year had found that less than one percent of 30 day equivalent fills exceeded the $600 threshold. CMS' initial analyses of 2015 prescription drug event (PDE) data indicate that this percentage now slightly exceeds one percent. CMS stated in the Call Letter that this new data coupled with the significant increase in the cost of Part D drugs since the last adjustment to the specialty tier threshold, supports an increase in the specialty tier threshold for CY 2017. To adjust the threshold, CMS proposed applying the annual percentage increase used in the Part D benefit parameter updates to the existing $600 threshold. Thus, for CY 2017, the specialty tier cost threshold would be $670. CMS stated it may or may not increase the threshold on an annual basis moving forward and that it will test the proposed increased threshold and continue to perform other analyses to assess whether threshold adjustments are necessary.	impact of this change to determine the true impact and any unintended consequences associated with the change.	the inclusion of Part D drugs on a specialty tier adversely affects drug utilization or enrollment decisions by certain types of beneficiaries, and 2) the impact of tiering exceptions for specialty tier drugs. o To support CMS's transparency initiatives, raise awareness, and educate beneficiaries on the cost of prescription drugs and their impact on the Part D program, CMS intends to add a hyperlink on the Medicare Plan Finder on Medicare.gov to the Medicare Drug Spending Dashboard, which is published on CMS.gov, and estimates implementation for 2017 Open Enrollment in fall 2016.

Overutilization Policies for Opioids & APAP

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
• **Discontinuation of APAP Reporting through the OMS –** As a result of drastic decreases in the annual number of APAP overutilizers since 2011, CMS proposed to discontinue the reporting of APAP overutilization tickets in the OMS beginning with the April 2016 OMS reports. CMS would continue to monitor APAP overuse for informational purposes.	• N/A	• Finalized as proposed
• **Compliance Activities and Changes to the OMS Opioid Overutilization Methodology –** CMS has identified opportunities to potentially modify the OMS opioid overutilization criteria in the future, including options to shorten the measurement period from 12 months to 6 months and use average MED rather than a count of 90 consecutive days of high MED. CMS solicited feedback from sponsors for further analysis, as well as comments on the proposed revisions to the OMS opioid overutilization criteria, on alternative ways to count prescribers, and considerations for implementation by sponsors. CMS may consider changes to guidance and the opioid overutilization criteria beginning in 2018.	• N/A	• CMS plans to continue to investigate potential modification of this measure for implementation in 2018 based on experience from compliance activities, additional analyses, and the CDC prescribing guidelines.
• **CMS' Expectation for Formulary-Level Cumulative Opioid POS Edits in CY 2017 –** Based upon results of a pilot commenced in 2015 to assess the feasibility and impact of formulary-level cumulative opioid edits at POS to prospectively prevent opioid overutilization, CMS expects that in CY 2017: o Sponsors who adjudicate pharmacy claims at POS would implement formulary-level cumulative MED POS edits effective January 1, 2017.PACE organizations who do not adjudicate claims at POS would be exempt from this expectation. In order to minimize claim rejections on false positives, CMS proposed that sponsors implement both soft and hard cumulative MED POS edits. o Sponsors' Pharmacy and Therapeutics (P&T) committees would develop the specifications for the soft and hard cumulative MED POS edits. • Beneficiaries with certain conditions, such as cancer, or those in hospice, would be exempted from the edits.	• AMCP is concerned that CMS is focusing on POS edits to address the opioid epidemic. AMCP believes this is a reactive approach and that CMS should focus on adopting proactive means of identifying at-risk beneficiaries, such as lock-in programs and expanding access of state prescription drug monitoring program (PDMP) data to health plans. • AMCP cautions CMS to carefully consider the timing of requiring the POS edits to be in place by January 1, 2017. It will be challenging for plans to complete their Pharmacy & Therapeutics Committee review and approval of MED-based POS edits for CY 2017, given that the final Call Letter with the final requirements will be released close to the date by which the CY 2017 formularies must be finalized and uploaded in HPMS. Therefore, AMCP requests that CMS consider delaying the implementation date to January 1, 2018 to	• CMS is revising this proposal after reviewing comments expressing concern for potential delay of beneficiary access to needed medications, the short time between the final Call Letter and the formulary submission deadline, and the need for more time to develop, test, and implement the edits. • For CY 2017, CMS expects sponsors to implement *either* a soft edit or a hard edit, or they may use both soft and hard edits as originally proposed in the draft Call Letter, and work toward a hard edit at a minimum in 2018 using reasonable controls to limit false positives. CMS will review 2016 and 2017 experience with these edits to inform content in the CY 2018 Call Letter. • In order to allow more time to develop and test the full edit specifications, Part D sponsors will have until September 1, 2016 to submit the detailed operational information to CMS for review. The

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
	allow additional time for the necessary P&T review and approvals, programming, and testing.	documentation must include information such as the type of edit(s), the MED level being utilized, exclusion criteria, and other screening information, as well as a written description of the program's mechanics, including the mechanism by which the edits will be resolved. • CMS clarifies the HPMS formulary submission requirements with respect to quantity limits. Opioids that have a quantity limit that is below any applicable FDA-approved maximum doses must be submitted as part of the HPMS formulary submission. However, if the only quantity restriction that will be applied at POS is a cumulative MED edit described in this section, a quantity limit does not need to be reflected on the HPMS formulary submission. The cumulative MED edit is considered to be a safety edit. This guidance updates that which is included in section 30.2.2.1 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. CMS also clarifies that non-formulary opioids can be included in the cumulative MED editing even though they are not included on the formulary.
• **Concurrent Use of Opioids and Buprenorphine –** CMS expects sponsors to implement a soft formulary-level POS edit when an opioid prescription is presented following the initiation of buprenorphine addiction therapy. At this time, CMS would not include a measure of concurrent use of opioids and buprenorphine in the OMS, but will continue to monitor utilization trends.	• N/A	• Finalized as proposed
• **Access to Medication-Assisted Treatment –** CMS clarified that MA plans have the same obligation to cover addiction treatment as is available under original Medicare and that Part D plans must ensure access to MAT that are covered under Medicare Part D. Currently only buprenorphine, buprenorphine/naloxone, and naltrexone are covered Part D drugs when used for medication-assisted	• N/A	• CMS states that absent a change in law, Medicare is unable to cover methadone for MAT under Medicare Part B or Part D. However, under Part C, MA organizations

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
treatment (MAT) of opioid addiction. Currently methadone is not covered by Part D for substance abuse treatment because it does not meet the Part D requirement that it "may be dispensed only upon a prescription" because it is administered in an inpatient addiction treatment program and is not dispensed in a pharmacy. The agency sought comment on whether this statutory requirement limiting access to coverage under Medicare Part D is a barrier to treatment. • Given the requirements imposed by the Drug Addiction Treatment Act of 2000 and Risk Evaluation and Mitigation Strategy for buprenorphine-containing products for MAT, Part D sponsors should not impose prior authorization criteria that simply duplicate these requirements. When prior authorizations are utilized, Part D sponsors must also carefully consider approval durations so as to not subject beneficiaries who are in need of these therapies to unnecessary hurdles. Part D formulary and plan benefit designs that hinder access, either through overly restrictive utilization management strategies or high cost-sharing, will not be approved.		may cover methadone for MAT as a supplemental benefit.
• **A Note About the CDC Guidelines for Prescribing Opioids for Chronic Pain –** CMS was monitoring the release of CDC prescribing guidelines for opioids and would consider potential revisions to CMS overutilization guidance and the OMS opioid overutilization methodology in the 2018 Call Letter.	• AMCP provided detailed comments to the CDC on the draft opioid prescribing guidelines in January 2016 encouraging the CDC to adopt a holistic, comprehensive, and multi-stakeholder approach among health care providers and patients to truly address the opioid epidemic. While AMCP believes the CDC's draft guidelines are a step in the right direction, AMCP has concerns with some of the recommendations and believes many important elements are either missing from the draft guidelines or can be improved upon, including: o Patient risk evaluation and assessment; o Lock-in programs; o Electronic prescribing; o Inter-professional team approach; o Prescription drug monitoring programs; o Opioid overdose antidotes; and o Safe storage and disposal of opioids.	• Given the publication of the final guidelines on March 15, 2016, CMS will consider potential revisions to CMS overutilization guidance and the OMS opioid overutilization methodology based on the CDC guidelines, for presentation in the 2018 Call Letter. In addition, CMS will consider recommendations set forth in the guideline during the CY 2017 formulary and benefits review

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
	• AMCP recommended that CDC consider these elements before finalizing and adopting the guidelines to ensure that the guidelines include the benefit of the experience gained from managed care pharmacy and the patient population it serves. • Finally, AMCP encouraged CMS to work collaboratively with CDC to develop a robust education strategy for prescribers once the opioid prescribing guidelines are finalized. AMCP believes educating prescribers of the new guidelines and their implications should be the primary responsibility of the agencies, and not of the individual plan sponsors or their P&T Committees.	

POS Pilot, Quantity Limits, & Mail Order

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
• **Point of Sale Pilot –** In the final 2016 Call Letter, CMS committed to conducting a pilot to help identify options for resolving certain point of sale (POS) claim rejections without the enrollee having to request a coverage determination from the plan. Currently, CMS is analyzing the final reporting from pilot participants to determine if there are any best practices or other operational changes plans could make related to POS rejections for the 2017 plan year. Some of the areas CMS may explore based on the pilot experience could include: o How CMS and Part D plans could reduce the volume of rejected claims on the front end by resolving certain issues before the prescription is sent to the pharmacy, such as: ▪ Encouraging electronic prescribing, particularly electronic prior authorization, or other efficiencies in the PA process for a subset of drugs where the information needed to satisfy the PA may be obtained in a streamlined manner; ▪ Making formularies more accessible to prescribers earlier in the process o How plans could employ proactive processes to resolve certain POS issues without the enrollee having to request a coverage determination, such as: ▪ Identifying an appropriate subset of rejected claims to target proactive outreach efforts; ▪ Designing outreach processes in a way that maximizes value while managing plan, pharmacy and prescriber resources, and program costs. • CMS welcomed feedback from Part D plans and other stakeholders on these issues.	• As a way to increase the use of electronic prior authorization (e-PA), earlier this year AMCP published results of a survey it conducted in late 2015 to identify potential outreach strategies that could be undertaken to speed and improve the adoption of e-PA. The findings suggest that many prescribers who use electronic prescribing (eRx) systems do not necessarily use the e-PA standard approved by the National Council of Prescription Drug Programs (NCPDP). Furthermore, the survey found that in many cases, prescribers do not distinguish the NCPDP standard e-PA from proprietary systems, such as non-standard email systems, web portal systems, or 7 electronic fax systems and therefore, may not be fully assessing the benefits of using standard e-PA. AMCP is working to proactively provide educational efforts on the benefit of standard e-PA to provide prescribers with more insight to evaluate the benefit and cost savings associated with using the NCPDP e-PA standard. Until prescribers appreciate the difference and see the value of the use of standard e-PA, AMCP predicts that adoption rates will be low. Simply asking Medicare Part D plans to encourage eRx and e-PA is not enough. AMCP recommends that CMS call attention to precisely the version of e-PA they would like to see adopted, and acknowledge that there may be marketplace confusion as to the	• After analyzing the results of the pilot and the comments received in response to the draft Call Letter, CMS states that additional exploration of these issues is warranted before proposing any regulatory changes, and therefore CMS will not impose changes to operational requirements for the 2017 plan year. • CMS will explore developing additional guidance and exploring additional requirements related to eRx and ePA to increase adoption of these technologies, testing the use of "smart edits" where information is or could be made available in real-time to allow certain claims to favorably auto-adjudicate at the POS, and further exploring how certain rejected claims may be targeted for proactive outreach in concert with existing rejected claim review and MTM requirements. • CMS reminds MA-PD plans of the new requirements at 42 CFR §422.112(b)(7), which became effective January 1, 2016. MA-PD plans are required to coordinate all Medicare benefits administered by the plan for prescription drugs that may be provided under Part B or Part D by establishing and maintaining a process to ensure timely and accurate POS transactions, and to issue a decision and authorize or provide the benefit as appropriate under Part B or Part D when a party requests a coverage determination. CMS intends to develop

CMS Proposal in 2017 Draft Call Letter	AMCP Comments & Recommendations on 2017 Draft Call Letter	2017 Final Call Letter
	differences. Only use of standard e-PA will help reduce POS rejections and improve the Medicare Part D member experience.	additional subregulatory guidance for MA-PD plans related to expectations for coordination of benefits when drug claims are rejected at the POS because of a B v. D prior authorization requirement.
• **Extended Days' Supply and First Fill Quantity Limits –** Starting in 2017, sponsors would have the option to designate specific drugs where only a one month supply will be covered for the initial fill, rather than a 2 or 3 month extended supply. Sponsors should use this designation for drugs in which there is the potential for a change in dose, or a discontinuation of therapy altogether, within the first month. Sponsors may not require beneficiaries to return to the doctor, or obtain a new prescription in order to convert the prescription into an extended days' supply. After the first month of therapy, the change should be "seamless" for the beneficiary.	• N/A	• Finalized as proposed, with the following clarification: o However, the specific drugs available for an extended days' supply on all but the first fill will not be included in an HPMS supplemental file for 2017. Sponsors should make clear in beneficiary materials information about first fill quantity limits and which drugs are affected.
• **Establishing Mail Order Protocols for Urgent Need Fills to Prevent Gaps in Therapy –** CMS has received beneficiary complaints about mail order pharmacies indicating that they will rush ship an urgently needed order, but the order does not arrive when promised or at all, potentially resulting in gaps in therapy. CMS expects Part D sponsors to work with their mail order pharmacies to develop and implement protocols for providing access to urgently needed medications. Further, CMS stated that beneficiaries should be informed of their options when requesting a rush order, with clear steps detailed in all applicable beneficiary materials.	• N/A	• CMS expects sponsors to have protocols in place to address how to handle urgently needed medication requests from beneficiaries by CY 2017 if not sooner and to be able to clearly communicate this to their beneficiaries. CMS will continue to monitor complaints for issues related to mail order or access to urgently needed medications.

Changes in the Payment Methodology for Medicare Part D for CY 2017

CMS Proposal in 2017 Draft Call Letter	2017 Final Call Letter
• **Update of the RxHCC Model –** CMS proposed that plan liability for non-LIS beneficiaries in the coverage gap would be 49% for non-applicable (generic) drugs and 10% plan liability for applicable (brand) drugs in the coverage gap.	• Finalized as proposed
• **Encounter Data as a Diagnosis Source for 2017 -** CMS proposed to continue calculating risk scores by blending two risk scores calculated as follows: one risk score calculated using diagnoses with dates of service of 2016 from the Risk Adjustment Processing System (RAPS) and FFS and another separate risk score using diagnoses with 2016 dates of service from the Encounter Data System (EDS) and FFS. CMS would blend the two risk scores, weighting the risk score from RAPS and FFS by 50% and the risk score from EDS and FFS by 50%. The shift in weighting continues the progression CMS began in 2012 of gradually moving towards relying exclusively on encounter data for plan-submitted diagnosis information. • For PACE organizations, CMS proposed to continue the same method of calculating risk scores as used for the 2016 payment year, which is to pool diagnoses from the following sources to calculate a single risk score (with no weighting): (1) EDS data valid for risk adjustment with 2016 dates of service; (2) RAPS data valid for risk adjustment with 2016 dates of service; and (3) diagnoses from FFS claims valid for risk adjustment.	• Finalized as proposed
• **Part D Risk Sharing -** CMS proposed that the risk percentages and payment adjustments for Part D risk sharing remain unchanged from CY 2016. 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.	• Finalized as proposed
• **Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2017 -** As required by statute, CMS proposed the Part D benefit parameters be updated in CY 2017 using the annual percentage increase (API) in average expenditures for Part D drugs per eligible beneficiary	• Finalized as proposed
• **Reduced Coinsurance for Applicable Beneficiaries in the Coverage Gap -** CMS proposed that the beneficiary coinsurance under basic prescription drug coverage be reduced to 51% 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 40% for applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit in 2017. • 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 specified 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 2017.	• Finalized as proposed
• **Dispensing Fees and Vaccine Administration Fees for Applicable Drugs in the Coverage Gap -** 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 2017, CMS proposes that applicable beneficiaries will pay 40% and plans will pay 60% of dispensing fees and vaccine administration fees for applicable drugs in the coverage gap.	• Finalized as proposed
• **Part D Calendar Year Employer Group Waiver Plans -** In light of rising specialty drug costs and their impact on EGWPs, CMS proposed modifying the current waiver 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 2014.	• Finalized as proposed