AMCP Academy of Managed Care Pharmacy®
www.amcp.org

SUMMARY

AMCP Summary: ***Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter***

Released: February 19, 2016

Comments Due: March 4, 2016

AMCP is pleased to see that CMS acknowledges AMCP in the 2017 Draft 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.

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

- **Tiers & Specialty Medications:**
  - CMS proposes applying the annual percentage increase used in the Part D benefit parameter updates to the existing $600 specialty tier threshold. Thus, for CY 2017, the specialty tier cost threshold will be $670. CMS states that 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.
    - AMCP seeks comments on how the change in specialty cost threshold will affect benefit design, including if certain medications may no longer be eligible for consideration on a specialty drug tier given the increase in threshold.
  - CMS proposes a non-preferred drug tier option that will allow for a drug mix regardless of brand/generic status. If approved, sponsors will have the option of selecting a non-preferred drug tier or non-preferred brand tier but not both. CMS encourages Part D sponsors to consider using a coinsurance for the non-preferred drug tier instead of a copay.
    - AMCP seeks comments on this proposal and the impact it would have on benefit design, including CMS' recommendation that Part D sponsors consider using a coinsurance vs. a copay.
- **Formulary-Level Cumulative Opioid POS Edits:**
  - CMS expects that sponsors who adjudicate pharmacy claims at POS will implement formulary-level cumulative MED POS edits effective January 1, 2017.PACE organizations that do not adjudicate claims at POS are exempt from this expectation. In order to minimize claim rejections on false positives, CMS proposes that sponsors implement both soft and hard cumulative MED POS edits.
  - CMS will not establish the cumulative MED levels, rather sponsors' Pharmacy and Therapeutics (P&T) committees will 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 seeks comments on the proposed parameters for formulary-level cumulative MED POS edits, including alternative thresholds, criteria to reduce false positives, and methods to assure prompt access to prescribed opioids when determined medical necessary.

- **Star Ratings & Display Measures:**
  - CMS does not propose new star ratings for 2017, but proposes several display measures for 2017 and beyond, including:
    - Post-discharge medication reconciliation;
    - Hospital readmissions for certain conditions;
    - Medication utilization in asthma, cardiovascular disease, and diabetes;
    - Care coordination;
    - Appropriate pain management;
    - Use of antipsychotics in dementia;
    - Depression treatment; and,
    - Evaluation of certain existing measures.
  - CMS proposes the removal of two measures from the 2017 Star Ratings:
    - High risk medication; and
    - Improving bladder control.
  - AMCP provided detailed comments to CMS in response to the memorandum titled "Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond" in December 2015 outlining the Academy's position on several of the proposed changes to the Star Ratings and display measures for 2017 and beyond. AMCP is pleased to see that many of its concerns were addressed in the Call Letter and that no drastic changes to the Star Ratings or display measures are being proposed for CY 2017. AMCP will reiterate these comments in its response to the Call Letter.
- **Enhancements to Medication Therapy Management (MTM):** CMS seeks to improve comprehensive medication review (CMR) completion rates and will continue to seek additional outcomes measures. AMCP is working with CMS and other stakeholders, including the Pharmacy Quality Alliance (PQA) and the HIT Collaborative to evaluate Medicare Part D MTM, electronic coding, and the development of outcomes measures.
- **CMS Audits of MTM Programs:** CMS proposes 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. AMCP seeks input from members and stakeholders regarding the scope of these audits.
- **Point of Sale (POS) Pilot:** CMS seeks feedback on a point of sale pilot it conducted, specifically on the value of electronic prescribing, electronic prior authorization (ePA), formulary access by prescribers, and other approaches to reduce POS rejections. AMCP has actively promoted efforts to adopt the ePA standard approved by the National Council of Prescription Drug Programs (NCPDP) as a way to improve efficiencies in the PA process. Furthermore, AMCP seeks to increase the adoption of e-prescribing of controlled substance prescriptions. AMCP will provide feedback and comments on these initiatives.

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

Comments on this proposal must be submitted to CMS by March 4, 2016 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 Wednesday, March 2nd. 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 March 3rd (2-3pm EST) to review the proposed policy provisions and changes to Star Ratings that are applicable to AMCP members in the 2017 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/.

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

Update of the RxHCC Model - page 48

- CMS proposes 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.

Encounter Data as a Diagnosis Source for 2017 - page 50

- CMS proposes 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 will 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 proposes 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.

Part D Risk Sharing - page 51

- CMS proposes 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.

Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2017 - page 53

- As required by statute, CMS proposes the following 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:

Table III-1. Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases

	Annual percentage trend for 2016	Prior year revisions	Annual percentage increase for 2017
API: Applied to all parameters but (1) and (2)	6.99%	4.45%	11.75%
July CPI (all items, U.S. city average): Applied to (1) September CPI (all items, U.S. city average): Applied to (2)	1.13% 1.67%	−1.26% −1.46%	−0.15% 0.18%

Part D Benefit Parameters

	2016	2017
Standard Benefit		
Deductible	$360	$400
Initial Coverage Limit	$3,310	$3,700
Out-of-Pocket Threshold	$4,850	$4,950
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (3)	$7,062.50	$7,425.00
Estimated Total Covered Part D Spending for Applicable Beneficiaries (4)	$7,515.22	$8,071.16

Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.95	$3.30
Other	$7.40	$8.25
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	$1.20
Other (6)	$3.60	$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	$2.95	$3.30
Other	$7.40	$8.25
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 ≤ $8,780 (individuals) or ≤ $13,930 (couples) (7) (category code 1)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.95	$3.30
Other	$7.40	$8.25
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $13,640 (individual) or $27,250 (couples) (7) (category code 4)		
Deductible (6)	$74.00	$82.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.95	$3.30
Other	$7.40	$8.25
Retiree Drug Subsidy Amounts		
Cost Threshold	$360	$400
Cost Limit	$7,400	$8,250

Reduced Coinsurance for Applicable Beneficiaries in the Coverage Gap - page 58

- CMS proposes 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 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 2017.

Dispensing Fees and Vaccine Administration Fees for Applicable Drugs in the Coverage Gap - page 58

- 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.

Part D Calendar Year Employer Group Waiver Plans - page 59

- In light of rising specialty drug costs and their impact on EGWPs, CMS proposes 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.

CY2017 Draft Call Letter

Star Ratings & Display Measures

AMCP provided detailed comments to CMS in response to the memorandum titled "Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond" in December 2015 outlining the Academy's position on several of the proposed changes to the Star Ratings and display measures for 2017 and beyond. As noted above, AMCP is pleased to see that many of its concerns were addressed in the Call Letter and that no drastic changes to the Star Ratings or display measures are being proposed for CY 2017.

Contracting Organizations with Ratings of Fewer Than Three Stars in Three Consecutive Years - page 100

- CMS proposes 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.

Changes to Measures for 2017 - page 102

- CMS is NOT considering adding any new measures for 2017 Star Ratings.
- CMS is proposing that 2017 Star Ratings methodology remain the same as the 2016 Star Ratings methodology with the exception of the following measures CMS proposes modifications to:
    - Improvement Measures (Part C & D) – page 102
        - Proposing that the methodology for incorporating measures into the calculation of the two improvement measures (one each for Part C and D) remains the same as in prior years, but be updated to account for measures with at least two years of data.
    - Appeals Timeliness/Reviewing Appeals Decisions Measures (Part C) and Appeals Upheld Measure (Part D) – page 103

        - 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 proposes 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.
    - Contract Enrollment Data (Part C & D) – page 103
        - 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.
    - Transition from ICD-9 to ICD-10 (Part C & D) – page 103
        - 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.
    - Appeals Upheld Measure (Part D) – page 103
        - Proposes 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.
    - Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D) – page 104
        - CMS proposes adding a detailed file during each HPMS plan preview period to list each contract's underlying denominator, numerator, and Data Validation score since exclusions are applied to the plan-reported MTM data.
        - CMS states 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. AMCP has established an MTM Advisory Group that is working with other stakeholders, including the Pharmacy Quality Alliance and the Pharmacy HIT Collaborative, to examine MTM electronic coding and policies to provide recommendations for improvements to MTM.

Removal of Measures from Star Ratings – page 104

- CMS proposes the following two measures be removed from the 2017 Star Ratings:
    - Improving Bladder Control (Part C) – page 104
        - CMS proposes that this measure be reported on the 2017 display page due to revisions in the questions used to assess it.
    - High Risk Medication (Part D) – page 105
        - CMS proposes 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.
        - CMS recommends that measure developers further review the HRM measure to understand the association between dual eligible/low income status and HRM use.

Data Integrity – page 106

- CMS proposes 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 proposes that audit criteria be developed and finalized based upon findings from pilot audits.

Impact of Socio-economic and Disability Status on Star Ratings – page 107

- 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 proposes 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 recognizes differences in legislative and regulatory requirements that result in unique challenges in Puerto Rico, and therefore, proposes moving forward and implementing the interim estimates for the LIS indicator instead of waiting for the availability of a different data source.

2017 CMS Display Measures – page 139

- CMS is proposing the following new or revised measures for the 2017 display page:
    - Timely Receipt of Case Files for Appeals (Part D) & Timely Effectuation of Appeals (Part D) – page 140
        - CMS proposes 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.
    - Medication Reconciliation Post (MRP) Discharge (Part C) – page 140
        - CMS proposes to expand MRP to all MA plans and members 18 years and older and include it the display page for 2017.
        - CMS 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 is planning on including the expanded MRP measure in the 2018 Star Ratings.
    - Hospitalization for Potentially Preventable Complications (Part C) – page 140
        - CMS proposes to include this measure on the 2017 display page and is planning to include it in the 2018 Star Ratings.
        - CMS 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.
    - Statin Therapy for Patients with Cardiovascular Disease (Part C) – page 140
        - CMS proposes 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 is planning to include it in the 2019 Star Ratings after gaining experience with the new treatment guidelines and metric.
    - Asthma Measures (Part C) – page 141
        - CMS proposes 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.
            - 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.
            - 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.
    - Statin Use in Persons with Diabetes (SUPD) (Part D) – page 141

        - CMS proposes 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 will be excluded from the denominator for the entire year.
        - Beneficiaries taking PCSK-9 inhibitors will NOT be excluded from the denominator.
        - CMS is planning to include it in the 2019 Star Ratings after gaining experience with the new treatment guidelines and metric.

New Measures – page 142

CMS is considering the following measures for the Star Ratings or display measures for 2018 and beyond:

- Care Coordination Measures (Part C) – page 142
    - 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.
- Depression Measures (Part C) – page 142
    - 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.
- Appropriate Pain Management (Part C) – page 143
    - 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.
- Use of Opioids from Multiple Providers or at High Dosage in Persons without Cancer (Part D) – page 143
    - 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:
        - 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.
        - 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.
        - 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.
- Antipsychotic Use in Persons with Dementia (APD) (Part D) – page 144
    - 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.

Changes to Existing Star Ratings and Display Measures and Potential Future Changes – page 145

- Medication Adherence for Hypertension (RAS Antagonists) (Part D Star Rating) – page 148
    - 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.
- MPF Price Accuracy (Part D Star Rating) – page 148
    - CMS is proposing several changes to this measure for the 2018 Star Ratings using 2016 PDE and MPF data:
        - Expansion of claims from solely 30-day supplies to include 28-34, 60-62, and 90-93 day supplies.
        - Use of the PDE-reported Pharmacy Service Type code in conjunction with the MPF Pharmacy Cost data to identify retail claims.
        - Changes to methodology by which price accuracy is calculated to also factor in how often PDE costs exceeded MPF costs.
- Drug-Drug Interactions (DDI) (Part D Display) – page 150
    - 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.
- Center for Medicare and Medicaid Innovation Model Tests – page 150
    - 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.
    - CMS welcomes comments on how national scope of many PDP contracts can be taken into consideration in evaluating options for addressing potential differences in performance between participating and non-participating plans.

Measurement and Methodological Enhancements – page 151

- 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.

Audits & Enforcement Provisions

Medicare Parts C & D Program Audits – page 151

- In response to stakeholder feedback, beginning with the 2017 audit protocols, CMS is proposing 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 welcomes comments on the proposed July release date and the consequences.

Medicare Parts C & D Enforcement Actions – page 153

- Civil Money Penalty (CMP) Calculation Methodology – page 153
    - 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.

- Compliance and Enforcement Actions Related to Part D Auto-Forwards – page 153
    - CMS notifies 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.
- Enforcement Actions Related to One Third Financial Audit Findings – page 154
    - CMS notifies 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.

Seeking Ways to Improve Value and Efficiencies in Medicare Advantage

CMS has made improving value and efficiencies in the Medicare program an important priority for 2016 and beyond. CMS is particularly concerned about Medicare Part B payments to physicians and medication costs, and place of service costs for medication administration. Given the current limitations in the traditional Medicare Part B program in making changes in these areas, CMS will focus on ways to change payment methodology under Medicare Advantage (MA), which includes Medicare Part B.

Cost Sharing/Bundling with Facility – page 171

- CMS is concerned about the transparency of costs sharing for MA beneficiaries. CMS notes 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 indicates 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.

Interoperability-MA Plans and Contracted Providers – page 173

- 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 seeks comment from the industry regarding their experience with these activities, including barriers to successful adoption.

Alternate Payment Models (APMs) – page 173

- 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 is seeking comments from the industry regarding challenges and concerns associated with the use of APMs in Medicare Advantage.

Improving Clinical Decision-Making for Certain Part D Coverage Determinations – page 183

- 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 requests comments from stakeholders on the value of proposing regulatory changes that would permit Part D plans to extend the adjudication timeframe for certain coverage determination requests for drugs subject to PA or ST where: (1) the plan has been unable to obtain needed clinical information from the prescriber despite reasonable efforts to do so, and (2) the adjudication timeframe has been impacted by a weekend or holiday. CMS is particularly interested in hearing from physicians and other prescribers on potential benefits and drawbacks of such a change and any potential unintended consequences.

Access to Preferred Cost-Sharing Pharmacies – page 185

- 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 reports increased PCSP access for 2016.
- CMS proposes 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.

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

In the Call Letter, CMS notes that the Center for Medicare and Medicaid Innovation (CMMI) has released a request for participation in a value based insurance design program and an expanded MTM test model but does not offer any additional insight on these demonstrations or the status of bids. CMS will provide additional information to participants in the expanded MTM test model as it becomes available.

Annual MTM Eligibility Cost Threshold – page 180

- The 2017 MTM program annual cost threshold will be adjusted based on the annual percentage and finalized in the 2017 Call Letter.

Annual MTM Submission and Approval Process – page 181

- Beginning with the CY 2017 submissions, CMS proposes to implement a modified annual MTM program review process and add attestations to the HPMS submission module as follows:
    - All Part D sponsors will continue to submit an MTM program description through HPMS each year. Sponsors will continue to submit change requests throughout the year.
    - Attestations of the Part D sponsor's compliance with Part D MTM program requirements will be added to the MTM submission module in HPMS.
    - 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.
    - A subset of MTM program submissions will 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 will continue to monitor beneficiary complaints, validation results of plan-reported MTM data, and CMS program audits of MTM programs.

Submission Requirements for Enhanced MTM Model Participants – page 182

- CMS proposes to waive the current MTM requirements for the PDPs approved to participate in the Enhanced MTM Model and data 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 – page 182

- 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 proposes 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 notes 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.

Tiers & Specialty Medications

CMS proposes several changes to tier structure, out-of-pocket costs, and specialty tier eligibility cost threshold after considering feedback from stakeholders and evaluating 2015 prescription drug event (PDE) data. AMCP seeks feedback from stakeholders on how the proposed changes will affect benefit design, especially for specialty medications.

Tier Labeling and Composition – page 186

- After receiving feedback from a number of plan sponsors, CMS is proposing a non-preferred drug tier option that will allow for a drug mix regardless of brand/generic status. The proposal is pending approval by the Office of Management and Budget, Office of Information and Regulatory Affairs. If approved, sponsors will have the option of selecting a non-preferred drug tier or non-preferred brand tier but not both.
- CMS notes 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 encourages 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.

Benefit Review – page 188

- 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 will 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 will calculate and publish the Part D TBC to support transparency related to the out-of-pocket beneficiary costs year over year.

Specialty Tiers – page 192

- 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

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 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 states 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 proposes 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 will be $670. CMS states 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.

Overutilization Policies for Opioids & APAP

CMS proposes several changes to the current overutilization policy including discontinuing the reporting of APAP overutilization in OMS and requiring formulary-level cumulative opioid POS edits developed by P&T committees. AMCP seeks comments on the proposed parameters for formulary-level cumulative MED POS edits, including alternative thresholds, criteria to reduce false positives, and methods to assure prompt access to prescribed opioids when determined medical necessary.

Discontinuation of APAP Reporting through the OMS – page 199

- As a result of drastic decreases in the annual number of APAP overutilizers since 2011, CMS proposes 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.

Compliance Activities and Changes to the OMS Opioid Overutilization Methodology – page 199

- 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 solicits 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. AMCP seeks input on the implications of this proposal.

CMS' Expectation for Formulary-Level Cumulative Opioid POS Edits in CY 2017 – page 202

- 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:
    - Sponsors who adjudicate pharmacy claims at POS will implement formulary-level cumulative MED POS edits effective January 1, 2017.PACE organizations who do not adjudicate claims at POS are exempt from this expectation. In order to minimize claim rejections on false positives, CMS proposes that sponsors implement both soft and hard cumulative MED POS edits.
    - Sponsors' Pharmacy and Therapeutics (P&T) committees will 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.
- CMS welcomes comments from sponsors on the proposed parameters for formulary-level, cumulative MED POS edits, including alternative thresholds, criteria to reduce false positives, and methods to assure prompt access to prescribed opioids when determined medical necessary.

Concurrent Use of Opioids and Buprenorphine – page 204

- 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 will not include a measure of concurrent use of opioids and buprenorphine in the OMS, but will continue to monitor utilization trends.

Access to Medication-Assisted Treatment – page 204

- CMS clarifies 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 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 seeks 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.

A Note About the CDC Guidelines for Prescribing Opioids for Chronic Pain – page 205

- CMS is monitoring the release of CDC prescribing guidelines for opioids and will 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.

POS Pilot, Quantity Limits, & Mail Order

Point of Sale Pilot – page 207

- 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:
    - 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
    - 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 welcomes feedback from Part D plans and other stakeholders on these issues, and expects to provide additional information in the final Call Letter.

Extended Days' Supply and First Fill Quantity Limits – page 208

- Starting in 2017, sponsors will 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.

Establishing Mail Order Protocols for Urgent Need Fills to Prevent Gaps in Therapy – page 209

- 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 states that beneficiaries should be informed of their options when requesting a rush order, with clear steps detailed in all applicable beneficiary materials.