March 2, 2018

Submit to: www.regulations.gov, Docket #: CMS-2017-0163

Mr. Demetrios Kouzoukas, Esq.
CMS Principal Deputy Administrator and
Director, Center for Medicare
U.S. Department of Health and Human Services
Room 314G
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Kouzoukas:

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Call Letter.

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the "Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Call Letter" released February 1, 2018 (hereafter, the "Advance Notice and Draft Call Letter" or the "Draft Call Letter"). PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the health insurance marketplaces.

PCMA appreciates several of the changes CMS proposes in the Draft Call Letter, which underscore the Agency's ongoing willingness to assess how to improve Part D by both reducing unnecessary burdens and making it more convenient and useful to beneficiaries, while at the same time helping address the major opioid crisis currently facing our nation and our Medicare population.

Highlights illustrating CMS's willingness to reassess policies include the following:

- PCMA is encouraged that CMS is proposing a number of steps to allow Part D plan sponsors to take more action to prevent over-prescribing of prescription opioids,

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particularly limiting the supply of prescription opioids to 7-days, in alignment with the CDC guidelines. PCMA urges CMS to address existing barriers and complexities to implementing this policy.

- PCMA is also very encouraged that CMS is open to considering changes to its current mail order refill consent policy which may create unnecessary burdens and interfere with improving medication adherence via automatic refill shipments.
- PCMA supports the proposed new Star Ratings measures and some of the changes to existing measures but opposes the change to the Medicare Plan Finder Price Accuracy measure and the proposed Beneficiary Access and Performance Problems replacement measure. PCMA recommends that CMS identify a methodology for achieving cut points thresholds that reflect industry standards.

We address in our attached comments below the issues in the order in which they appear in the Advance Notice and Draft Call Letter. We also address some Call Letter process issues for CMS consideration.

We appreciate the opportunity to comment and we urge CMS to adopt PCMA's recommendations as set forth in our comments. If you have any questions, or if we can provide you with any further information, please do not hesitate to contact us.

Sincerely,

Wendy Krasner

Wendy Krasner
Vice President – Regulatory Affairs

Attachment

cc: Cheri Rice
Amy Larrick
Jennifer Shapiro
Kristin Bass, PCMA
Mona Mahmoud, PCMA

PCMA Comments on the Advanced Notice and Draft Call Letter

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CY 2019 Advance Notice

Draft CY 2019 Call Letter

PCMA

ADVANCE RATE NOTICE

1. Encounter Data as a Diagnosis Source for 2019

CMS Proposal: For 2019, CMS proposes to calculate risk scores by adding 25% (up from 15% in 2018) of the risk score calculated with diagnoses from encounter data (supplemented with RAPS inpatient data) and FFS with 75% (down from 85% in 2018) of the risk score calculated from RAPS data and FFS diagnoses.

Discussion: We are very concerned about the proposal to increase the percentage of risk scores calculated based on encounter data. In January 2017, Avalere analyzed eight Medicare Advantage Organizations representing 1.1 million beneficiaries across 30 unique plans and found that average risk scores using encounter data were 16% lower in the 2016 payment year compared to scores under RAPS.[1] Likewise, the GAO found in January 2017 that CMS has yet to fully validate the accuracy of encounter data and that payments based on non-fully validated encounter data bring into question the "soundness of billions of dollars in Medicare expenditures…."[2] Notably, the GAO found that CMS had not yet reviewed medical records to verify diagnoses and services listed in the encounter data, and that many stakeholders expressed concern about CMS's ability to properly identify diagnoses used for risk adjustment. The GAO recommended that CMS establish specific plans and time frames for addressing the current limitations of encounter data, but the Agency only offered technical comments in response to the GAO report. Considering the remaining challenges with encounter data and the agency's limited progress in addressing them, CMS should avoid greater reliance on encounter data until such data can be fully assessed and verified.

PCMA Recommendation: CMS should not increase the risk score calculations based on encounter data until the range of problems that have been identified with the data are fully addressed and resolved.

2. Part D Risk Sharing

CMS Proposal: CMS proposes to maintain the risk sharing corridors at the existing levels. Although CMS notes that it has the statutory authority to widen the risk corridors, the Agency notes that risk sharing amounts continue to fluctuate from year to year.

[1] *See* "Rise RAPS-EDS Collaboration Research Project Executive Summary," Avalere Health (Jan. 26, 2017).
[2] "Medicare Advantage: Limited Progress Made To Validate Encounter Data Used To Ensure Proper Payments," GAO (Jan. 17, 2017).

Discussion: We appreciate that CMS acknowledges it is not appropriate to adjust the risk sharing parameters at this time as Part D sponsors have yet to significantly improve their ability to predict Part D expenditures.

PCMA Recommendation: PCMA supports CMS's decision to maintain the current risk sharing corridors.

Section I: Parts C and D – ENHANCEMENTS TO THE 2019 STAR RATINGS AND FUTURE MEASUREMENT CONCEPTS

1. General/Technical Expert Panel (TEP)

CMS Proposal: CMS states that, after the 2019 Call Letter is finalized, RAND Corporation will establish a technical expert panel (TEP) in 2018 comprised of representatives across various stakeholder groups to obtain feedback on the Star Ratings framework, topic areas, methodology, and operational measures.

Discussion: PCMA is pleased with the various early signals by this Administration that it recognizes that the entire Star Ratings framework and process are due for a complete review and update. CMS established the current Star Ratings System and has used the Star Rating measures for the past decade. PCMA strongly supports a complete review of all aspects of the Star Ratings system, including the framework, topic, methodology, and operational measures.

As Part D plan sponsors and their PBMs have the greatest amount of direct experience in working with the Part D Star Ratings, representatives from Part D plans should have broad representation on the TEP. It will be important for RAND to include Part D plan and PBM representatives with various types of experience including both clinical, analytical, and operational experience.

PCMA Recommendation: PCMA supports the CMS decision to have a TEP established to obtain feedback on the Star Ratings framework, topic areas, methodology, and operational measures; PCMA recommends that representatives from Part D plans and PBMs have broad representation on the TEP. In order to improve Star Ratings program transparency and predictability, CMS should ensure the TEP's areas of focus will include the crucial issues of a multiyear strategic plan for adoption and retirement of Star Ratings measures, pre-determined cut points for Star Ratings measures, and ways to make the Categorical Adjustment Index (CAI) methodology more impactful.

2. Reminders for 2019 Star Ratings

CMS Proposal: CMS assigns stars for each numeric measure score by applying one of two methods: clustering or relative distribution with significance testing. CMS indicates that the cut points to determine star assignments for all measures and case-mix coefficients for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and Health Outcomes Survey (HOS) will be updated for 2019 Star Ratings using the most current data available.

Discussion: The Star Ratings system is designed to provide information to the beneficiary that is a true reflection of the plan's quality and enrollee experience. PCMA has significant concerns that the current clustering methodology to assign measure cut point thresholds misclassifies industry performance, and, therefore, undermines the integrity and value of the Star Rating system.

A number of observations underscore the flaws with the current methodology:

a. Across Star Ratings measures, cut point thresholds often move independently of industry performance. While industry trends across Part D plans have demonstrated consistent annual Star Rating improvements, cut point thresholds increase and decrease at different rates.
b. Outlier contracts, which tend to have low enrollment, have the ability to establish the 5- or 2-star cut point thresholds due to highly differentiated levels of high or low performance. The performance of these contracts is often volatile and not sustained from year-to-year. Additionally, contract characteristics, such as enrollment and LIS membership, are strongly correlated to performance on Star Ratings. Contracts with lower enrollment and lower LIS membership establish 5-star cut point thresholds.
c. Many Part D plans demonstrate consistent year-over-year improvements but still drop a Star Rating level. In contrast, on some measures, Part D plans whose performance declined year-over-year improve by a Star Rating level.
d. In some measures, a lack of differentiation exists in Part D plan performance with greater than 90 percent of the industry earning high performance. Instability in cut point thresholds in performance can mask low or declining performance.

To illustrate these concerns, we offer the following example: Specifically, on the PDP D13: Adherence Statin measure, the cut point thresholds increased at a greater rate than industry improvement. The industry maintained a consistent rate of improvement of 1.3 percent between 2017 and 2018; however, the PDP D13 Star Rating cut point thresholds increased by up to 5 percent.

If CMS continues the current methodology, CMS should make adjustments to put a lower weighting on low enrollment plans or to exclude such plans from the clustering methodology calculations. PCMA encourages CMS to address the need to make adjustments to its methodology for determining cut points prior to the 2019 measurement year.

PCMA also requests that CMS make threshold cut point information available to Part D plan sponsors earlier, preferably at the start of the year. By the time plan sponsors have cut point information, they only have four months to refocus efforts on specific measures.

PCMA Recommendation: To achieve cut point thresholds that reflect industry performance, CMS should identify a methodology prior to the 2019 measurement year to determine cut points that more accurately reflect industry performance and that is not as susceptible to influence by outliers. In addition, CMS should make threshold cut point information available to plan sponsors earlier in the year.

3. New Measures for 2019 Star Ratings

a. Statin Use in Persons with Diabetes (SUPD)

CMS Proposal: CMS proposes to include the SUPD measure as a Part D Star Ratings measure for 2019. The measure is defined as the percentage of patients between 40 – 75 years old who received at least two diabetes medication fills and also received a statin medication during the measurement period. Beneficiaries in hospice or with end-stage renal disease (ESRD) are excluded. CMS proposes to add the SUPD measure to the 2019 Star Ratings (based on 2017 data) with a weight of 1 for the first year. In future years, CMS proposes a weight of 3 as an intermediate outcome measure.

Discussion: The SUPD measure is clinically appropriate and operationally reasonable.

PCMA Recommendation: PCMA supports the CMS proposal to add the SUPD measure to the 2019 Star Ratings with a weight of 1 for the first year. CMS should use the formal rulemaking notice and comment period before any future changes are made to this measure, including any change to the weight of the measure.

b. Statin Therapy for Patients with Cardiovascular Disease

CMS Proposal: CMS proposes to include the Statin Therapy for Patients with Cardiovascular Disease as a Part C Star Ratings measure for the 2019. The measure is defined as the percentage

of males 21 – 75 years of age and females 40 – 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. The measure allows for exclusion of certain conditions that may indicate statin intolerance.

Discussion: The Statin Therapy for Patients with Cardiovascular Disease measure as proposed is clinically appropriate and operationally reasonable. However, PCMA is aware that NCQA may modify this measure to add additional components. The measure is currently a gap measure (one fill per year to be considered compliant); however, the measure references HEDIS technical specifications. NCQA has proposed updating the HEDIS measure to make this an adherence measure to score favorably only for those beneficiaries that remained on a statin medication for 80 percent of the treatment period.[3]

PCMA is concerned that this measure may be added and then updated to align with the proposed NCQA changes. Besides the two proposed statin measures, CMS also has the statin adherence measure for cholesterol that is currently a Part D Star Ratings measure. There will be significant overlap among the beneficiaries who qualify for all three measures.

PCMA Recommendation: PCMA supports the CMS proposal to add the Statin Therapy for Patients with Cardiovascular Disease measure to the 2019 Part C Star Ratings with a weight of 1 for the first year. PCMA requests that CMS consider whether any future additional components are appropriate for Star Rating measures.

4. Changes to Measures for 2019

a. Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications

CMS Proposal: CMS proposes to expand data sources for identifying all Part D enrollees with ESRD for exclusion to include ICD-10-CM codes in Part A/B claims and Risk Adjustment Processing System (RAPS) RxHCCs.

PCMA Recommendation: PCMA supports the proposed change to the Medication Adherence for Hypertension (RAS Antagonists) and Medication Adherence for Diabetes Medications exclusions.

[3] NCQA, HEDIS/CAHPS Measures Proposed for Health Plan Accreditation for Scoring in 2019. (Public comment document, comments were due December 15, 2017). https://www.ncqa.org/Portals/0/PublicComment/HEDIS_CAHPS%20Measures%20for%20Health%20Plan%20Accreditation%20for%20Scoring%20in%202019%20Overview_FINAL.pdf?ver=2017-12-06-130040-707

b. Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medication, Medication Adherence for Cholesterol (Statins)

CMS Proposal: For use in the Proportion of Days Covered (PDC) adjustment for inpatient stays and hospice enrollment (MA-PD and PDP) and SNF (PDP), in cases where the beneficiary has consecutive stays where the admission date of the second stay is one day after the discharge date, CMS proposes to concatenate consecutive stays to create a single admission and discharge date for the PDC adjustment.

PCMA Recommendation: PCMA supports the proposed change for the Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) to concatenate consecutive stays to create a single admission and discharge date for the PDC adjustment.

c. Medicare Plan Finder (MPF) Price Accuracy

CMS Proposal: CMS proposes the following changes:

1. Factor both how much and how often PDE prices exceeded the prices reflected on the MPF by calculating a contract's measure score as the mean of the contract's Price Accuracy and Claim Percentage scores.
   - Price Accuracy = magnitude of differences found between POS PDE prices to plan-reported MPF prices. (Total amount that PDE is higher than MPF + Total PDE cost)/(Total PDE cost)
   - Claim Percentage = percentage of all PDEs that meet the inclusion criteria with a total PDE cost high than total MPF cost to determine the frequency of differences found. (Total number of claims where PDE is higher than MPF)/(Total number of claims)

2. Increase the claims included in the measure: Expand the days' supply of claims included from 30 days to 28-34, 60-62, or 90-100 days. Identify additional retail claims using the PDE-reported Pharmacy Service Type Code.

3. Round a drug's MPF cost to 2 decimal places for comparison to its PDE cost. The PDE cost must exceed the PF cost by at least a cent ($0.01) in order to be counted towards the accuracy score. Previously, a PDE cost which exceeds the MPF cost by $0.005 would be

counted. A contract's score is not lowered if PDEs are priced lower than MPF displayed pricing.

4. The modified measure will be a display measure for 2020 and 2021; CMS intends to consider adding this measure for the 2022 Star Ratings. CMS proposes to continue the current MPF measure in the Star Ratings until the modified measure is incorporated.

Discussion: PCMA continues to strongly advocate that the frequency of price changes is not an appropriate measure of concern to beneficiaries. Beneficiaries are impacted when the pricing data available on the MPF is significantly different than the price charged at POS and reflected in the PDE data. In the past several years, Part D plan performance remained consistently strong on the MPF Price Accuracy magnitude calculation. Nearly 100 percent of MA and PDP plans scored 98 (4 Stars) and 99 (5 Stars) on the measure.

The frequency of pricing differences between the data available on the MPF and the price reflected in the PDE data is due to established CMS timelines for MPF updates. Files are prepared and submitted by a Part D plan according to the CMS-issued calendar and guidelines which do not allow submissions outside the specified bi-weekly schedule. CMS posts files two weeks after submission which are then displayed on MPF for two weeks. When a beneficiary views drug pricing data on MPF, the data are typically between 19 to 31 days old. Pricing data for the MPF display are based on a single reference/proxy NDC and are compared to an expanded list of NDCs on the PDEs. Drug costs vary by NDC, even those with same strength or dosage form, and drug prices can change daily. This variability leads to unavoidable inconsistencies between a Part D plan's submitted price and the price on the claim or PDE record.

Rather than continue to evaluate Part D plan sponsors negatively when the timing construct creates a situation where MPF pricing information will never be 100 percent accurate, it would be more reasonable for CMS to consider an alternative approach. Specifically, CMS should include language on the MPF that indicates that the pricing data may be up to two weeks old and thus may not reflect the prices that beneficiaries experience at the time a prescription is dispensed.

PCMA urges CMS to convene a group of experts, including representatives from Part D plan sponsors and PBMs, to develop appropriate improvements in the measure. We believe that by working together we can develop more meaningful approaches to beneficiary protections, as well as provide more accurate information on drug pricing.

CMS should reconsider whether frequency is an appropriate component to be added to the MPF Price Accuracy measure. If a frequency measure must be used, CMS should revise frequency

calculations to ensure that the measure is relevant to beneficiaries and does not include price differences of less than or equal to something in the range $0.50 – $1.00. On the proposal to increase the claims included in the measure by expanding the days' supply of claims included, CMS should clarify whether the change would be made to impact the 2019 Star Ratings MPF Price Accuracy Measure.

PCMA Recommendation: PCMA opposes the CMS addition of a frequency component to the MPF Price Accuracy Measure. CMS should convene a group of experts to assess the most appropriate measurement of MPF Price Accuracy to reflect performance information that is both meaningful to beneficiaries and accurate.

d. Members Choosing to Leave the Plan

CMS Proposal: CMS proposes to expand the exclusions to include PBP service area reductions that result in the unavailability of PBPs that the enrollee is eligible to move to within the contract.

Discussion: PCMA encourages CMS to consider removing this measure from the Star Ratings measure set. The disenrollment reason codes do not provide insight as to why beneficiaries choose to leave a plan. Accordingly, the Members Choosing to Leave the Plan (Voluntary Disenrollment) measure does not accurately reflect the beneficiary's experience or dissatisfaction with the plan's quality of service. This measure is primarily influenced by plan pricing strategies and competitive market dynamics that result in beneficiaries choosing to leave the plan during the Annual Enrollment period (AEP). If the intent is to measure pricing strategies and competitive market dynamics, then the measure is incomplete as it does not account for LIS beneficiaries that are re-assigned during AEP due to loss of benchmark status. The Voluntary Disenrollment measure should be moved to the Display Page as CMS considers alternative approaches to measure beneficiary experience in a more effective manner.

PCMA Recommendation: CMS should move the Voluntary Disenrollment (Members Choosing to Leave the Plan) measure to the display page as CMS considers alternative approaches to measure member experience in a more effective manner.

5. Removal of Measures from Star Ratings

CMS Proposal: CMS proposes to retire the current Beneficiary Access and Performance Problems (BAPP) measure. For the 2019 Star Ratings, CMS proposes to modify the BAPP measure to include only Compliance Activity Module (CAM) data, which includes: notices of non-compliance, warning letters, and ad-hoc corrective action plans (CAP) and the CAP severity.

The revised BAPP measure would be on the display page for 2019. CMS solicits input on the utility of this measures focused only on notices of non-compliance, warning letters and ad-hoc CAPs and their severity.

Discussion: PCMA supports the CMS proposal to retire the current BAPP measure and appreciates CMS for the dialogue on this issue over the past year. As we have indicated previously, PCMA opposes the inclusion of audit findings and enforcement actions within the Star Ratings program. The information presented in the Draft Call Letter provides enough details on how CMS plans to modify the measure to include only CAM data to allow stakeholders to fully evaluate the proposed measure methodology. PCMA requests that CMS provide more complete information and the proposed measure methodology before moving forward with the revised measure as a display measure for 2019.

Based on the content that is available in the Draft Call Letter, PCMA opposes the revised BAPP measure as using CAM data continues to rely on documents generated based on audit results. The use of such documents creates an unlevel playing field. Since not all plans are audited during a given review period, it does not account for the audit/review lifecycle of plans. For every other current Star Ratings measure, performance data is collected for all plans annually using a consistent methodology and data source. In addition, CMS itself has acknowledged that there is no correlation between plan audit performance and Star Rating measure performance in its 2015 Part C and Part D Program Audit and Enforcement Report: "While Star Ratings remain a valuable measure of quality and beneficiary experience, they evaluate different aspects of sponsors' operations and delivery of the benefit. Therefore, both Star Ratings and audit scores are valuable measures."[4]

PCMA Recommendation: PCMA supports the CMS decision to retire the current BAPP measure. CMS should provide more complete information and the proposed measure methodology before moving forward with the revised measure as a display page measure for 2019. Based on the limited information available in the Draft Call Letter, PCMA opposes the revised BAPP measure because the use of CAM data continues to rely on documents generated based on audit results.

6. Data Integrity

CMS Proposal: CMS indicates that its longstanding policy has been to reduce a contract's measure to 1 star if CMS determines that a contract's measure data are incomplete, biased or

[4] CMS, "2015 Part C and Part D Program Audit and Enforcement Report," September 6, 2016.

erroneous. CMS will continue to conduct reviews to identify incomplete or biases Star Ratings measure data. The Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) is calculated using data reported by plan sponsors and validated via an independent data validation using CMS standards. Contracts that did not score at least 95 percent on data validation and/or were not compliant with data validation standards are not rated in this measure, and the contract's measure score is reduced to 1 star. CMS proposes to define a contract as being non-compliant if it either receives a "no" or a 1, 2, or 3 on the 5-point Likert scale in the specific data element's data validation.

Discussion: PCMA does not have specific concerns with the CMS proposal as presented. However, if there are data validation issues, CMS should advise the Part D plan sponsor in a transparent and timely manner. An opportunity to appeal audit findings prior to any adjustments would be welcome and is encouraged.

In addition, PCMA encourages CMS to be concerned with all data integrity issues and not only data integrity issues within Part D plans. CMS has had its own data integrity problems with CMS vendors, including data integrity issues with the MPF Price Accuracy measure in 2018 and vendor data integrity issues with the TTY measure. We encourage CMS to address the issue of data integrity more broadly.

PCMA Recommendation: CMS should advise plan sponsors in a transparent and timely manner of any data validation issues and allow for an opportunity to appeal audit findings. PCMA encourages CMS to address the issue of data integrity issues more broadly and to examine its own data integrity issues.

7. Proposed Scaled Reductions for Appeals IRE Data Completeness Issues

CMS Proposal: At present, there are two Part D measures that rely on data submitted to the IRE (Appeals Auto-Forward and Appeals Upheld). Contracts identified during an audit review to have systematic issues with completeness of IRE data have had their appeals measures reduced to 1 star. In response to stakeholder concerns, CMS initiated the Timeliness Monitoring Project (TMP) in 2017.

CMS is now proposing statistical criteria to reduce a contract's Star Ratings for data that are not complete or lack integrity using TMP data or audit. CMS has developed a methodology for reductions that reflects the degree of the data accuracy issue for a contract instead of a one-size-fits-all approach; the methodology would employ scaled reductions based on the degree of missing IRE data. The most severe reduction would be a four-star reduction, thus resulting in a

measure-level rating of 1 star for the associated appeals measures. CMS indicates that its proposed scaled reduction methodology would be a three-stage process using the TMP data or audit to determine: first, whether a contract may be subject to a potential reduction; second, as a basis for the determination of the estimated error rate; and, finally, whether the estimated value is statistically greater than the cut points for reductions of 1, 2, 3, or 4 stars. CMS indicates that the reduction would be applied to the contract's associated appeals measure-level Star Ratings.

Discussion: PCMA supports the CMS modification to use a scaled reduction based on the degree of missing IRE data instead of the previous one-size-fits all approach. However, the additional change effectively modifies the appeals Star Ratings measure from a timeliness measure to a timeliness and data integrity measure; this is not unique to the IRE. The proposed changes have the effect of modifying the measure significantly. PCMA asks that CMS clarify whether the 2018 cycle results will be used for the 2019 Star Ratings measure or whether 2017 cycle results will be used. PCMA also asks CMS to clarify whether CMS will allow Part D plan sponsors the opportunity to obtain information on which cases are considered untimely, and allow plans to address and improve processes.

PCMA Recommendation: PCMA supports the CMS proposal to use a scaled reduction based on the degree of missing data but requests clarification on timing and information that will be available to Part D plan sponsors. The change to a scaled reduction is a significant modification, and, therefore, CMS should move the measure to the display page for one year.

8. 2019 Categorical Adjustment Index (CAI) Values

CMS Proposal: CMS indicates that Part D plans will have one adjustment for the Part D summary rating. CMS provides the description of each of the final adjustment categories for the Part D summary for PDPs and the associated value of the CAI per final adjustment category in Table 15 (p. 132).

Discussion: PCMA appreciates efforts by CMS to address social risk issues affecting health outcomes in beneficiary populations and the work to make adjustments in the identified measures. PCMA notes the limited effect of the CAI on plans with high-risk beneficiary populations and requests additional attention be focused on improving this or other methods for recognizing beneficiary and community characteristics on measure results.

PCMA Recommendation: PCMA appreciates the work done by CMS on the CAI adjustments and requests that CMS continue its important work in this area.

9. Disaster Implications

CMS Proposal: CMS proposes to adjust the 2019 and 2020 Star Ratings to take into account the effects of extreme/uncontrollable circumstances that occurred during the performance period, such as the disasters that occurred during the 2017 performance period.

Discussion: PCMA supports CMS efforts to address the impact on beneficiaries and Star Rating measures. However, we are concerned that the criteria outlined by CMS that greater than 25 percent of total membership must be in the impacted service area to be biased against larger contracts serving populations spread across multiple regions. PCMA recommends that CMS develop a method that adjusts for impacted membership in a more representative manner at the enrollee level. One suggested alternative would be for enrollees identified as living within the impacted geographic area would be removed from the measurement calculation. This alternative would ensure that all affected contracts receive an adjustment that is commensurate with the level of impact to the plan performance and would maintain an approach consistent with other exclusion criteria used in Star Ratings measures. This approach would also ensure that Star Ratings performance is representative of performance during the measurement period.

PCMA Recommendation: PCMA supports CMS efforts to address the impact on beneficiaries and Star Rating measures. CMS should develop a method that adjusts for impacted membership in a more representative manner at the enrollee level.

10. 2019 CMS Display Measures

a. High Risk Medications (HRM)

CMS Proposal: CMS proposes to use the updated PQA HRM drug list. CMS also proposes to adopt a change for the numerator (beneficiaries with at least two fills of the same HRM drug on different days of service) for the 2019 display measures.

PCMA Recommendation: PCMA supports the CMS proposal to use the updated PQA HRM drug list and to adopt the proposed change for the numerator. PCMA continues to support the use of the HRM measure as a display measure only. As acknowledged by CMS in previous years, the HRM measure is not appropriate as a Star Rating measure.

b. Drug-Drug Interactions (DDI)

CMS Proposal: The DDI measure is the percent of beneficiaries who received a prescription for a target medication during the measurement period who were also dispensed a concurrent prescription for a contraindicated medication. CMS proposes to use the PQA list revised in 2018 for the 2019 display measure using 2017 data.

PCMA Recommendation: PCMA supports the CMS proposal to use the updated PQA list for the 2019 display measure.

c. Antipsychotic Use in Persons with Dementia (APD)

CMS Proposal: The APD measure is the percentage of beneficiaries 65 or older with dementia who received prescriptions for antipsychotics without evidence of a psychotic disorder or related condition. The APD measure includes an overall measure rate and breakouts for community only and LTC residents. CMS proposes to display the rates for the two population breakouts on the 2019 display page (in addition to the overall APD rate). CMS indicates that it will assess adding the APD measure to the Star Ratings in the future.

Discussion: While PCMA does not have concerns with the changes being made as the measure will be used on the display page, we do have concerns that should be addressed before CMS considers the APD measure as a Star Ratings measure. Specifically, PCMA encourages CMS to work with measure developers to explore the ways to mitigate the impact of geographic variation in antipsychotic prescribing. We urge CMS to consider the system-level factors impacting antipsychotic use that are largely out of the control of Part D plan sponsors. First, antipsychotics are one of the "classes of clinical concern," known as the protected classes, thus generally limiting the use of prior authorization by Part D plan sponsors. Second, there are noted geographic variations in antipsychotic use. One study found the weighted average propensity of prescribers to adopt new antipsychotics varied four-fold across hospital referral regions (HRRs).[5]

PCMA Recommendation: PCMA does not have concerns with the two population breakouts as the measure will be used on the display page. However, PCMA believes that this measure does not take into consideration all clinical information and would like to have the opportunity for additional discussion before CMS adopts this as a Star Ratings measure.

[5] Donohue, Julie M., et al. "Regional variation in physician adoption of antipsychotics: Impact on US Medicare expenditures." The journal of mental health policy and economics 19.2 (2016): 69.

d. Use of Opioids from Multiple Providers and/or at High Dose in Persons without Cancer

CMS Proposal: PQA approved non-substantial changes to the three measures. The rates now have separate names. MED changed to "morphine milligram equivalents." CMS would add only the OHDMP measure to the 2019 Part D display page, based on commenter feedback. All three PQA opioid measures will be reported through the Patient Safety reports.

PCMA Recommendation: PCMA supports the changes and the use of only the OHDMP measure on the 2019 Part D display page. PCMA further supports continued work on opioid measures.

e. Formulary Administration Analysis (FAA) measure

CMS Proposal: This measure uses the results of the FAA to evaluate whether Part D sponsors are appropriately adjudicating drug claims consistent with Part D requirements and approved benefits. This measure display will change from a percentage with one decimal place to being displayed as a percentage with two decimal places.

Discussion: PCMA has concerns with the display measure using the results of the FAA. Specifically, the claim samples that are reviewed are targeted samples (like other CMS audits); therefore, the universe of claims is already skewed toward potential issues. As indicated in previous communication, PCMA opposes the use of measures based on audit results and, therefore, does not believe that this is an appropriate measure.

PCMA Recommendation: PCMA encourages CMS to remove the FAA measure from the display page.

11. Forecasting to 2020 and Beyond

a. "Topped Out" Measures

CMS Proposal: CMS will consider which measures are topped out or have little variation across contracts to transition them to the display page.

Discussion: PCMA has the following comments on the topped out measures:

- CMS should determine how it handles topped out measures based on the merit and benefit of the individual measure and not specifically on whether the measure is topped out.
- Many topped out measures evaluate fundamental components of quality, and, as such, should not be removed from the Star Ratings measure set.
- CMS should develop an agency-wide policy related to topped out measures as this is an issue in all CMS programs and has been discussed in the recently finalized rule providing updates for the second and future years of the Quality Payment Program (QPP).[6]
- Topped out measures, like other measures, should be re-evaluated to determine if the measure still provides merit. CMS may consider decreasing the weighting of a topped out measure rather than discontinuing the measure if it no longer provides a benefit.
- As noted by CMS in discussing comments it received on the 2017 QPP proposed rule, reasons to maintain topped out measures include:
  - Topped out measures may serve to motivate continued high-quality care.
  - Declines in measure will not be captured if a measure is eliminated.
  - Providing beneficiaries with information about high performance is important.

PCMA Recommendation: CMS should determine how it handles topped out measures based on the merit and benefit of the individual measure and not specifically on whether the measure is topped out.

b. Medication Adherence for Cholesterol (Statins)

CMS Proposal: CMS indicates that it is considering a potential change to the existing Part D measures, Medication Adherence for Cholesterol (Statins). PQA updated this measure for 2018 to exclude beneficiaries with ESRD. CMS would apply this exclusion to the 2020 Star Ratings (based on 2018 data), in the same manner that the ESRD exclusion is applied to the Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Statin Use in Persons with Dementia measures.

PCMA Recommendation: PCMA supports the proposal to exclude beneficiaries with ESRD from the Medication Adherence for Cholesterol (Statins) measure.

[6]Centers for Medicare & Medicaid Services, "Medicare Program: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models." Final rule with comment period. *Federal Register*, Vol. 81, No. 214, November 4, 2016. (p. 77139) https://www.gpo.gov/fdsys/pkg/FR-2016-11-04/pdf/2016-25240.pdf

c. MTM Program Completion Rate for CMR Measure

CMS Proposal: PQA updated this measure to include a new denominator exception: for patients eligible for CMR with fewer than 61 days of continuous enrollment in the MTM program, exclude them from denominator if they did not receive a CMR, or include them in the denominator and numerator if they received a CMR. CMS plans to apply this denominator exception to the 2020 Star Ratings (2018 data).

PCMA Recommendation: PCMA is pleased with the PQA update to the MTM Program Completion Rate for CMR Measure and supports the proposal to incorporate this denominator exception in the 2020 Star Ratings.

d. CMMI

CMS Proposal: CMS notes that some stakeholders have expressed concern regarding the potential for the improvements in quality resulting from the MA-VBID and Part D Enhanced MTM model tests to adversely influence the Star Ratings of contracts that are ineligible to participate. For MA-VBID, CMS is considering the option of excluding VBID participants' data when calculating the cut points for relevant measures. Part D sponsors in the Enhanced MTM model test must establish their MTM programs in compliance with current requirements for the remaining plans under each Part D contract. MTM Program CMR Rates will be calculated using available plan-reported data from the remaining plans. CMS will analyze if this approach significantly advantages or disadvantages Enhanced MTM model participants and evaluate potential adjustments, including establishment of different cut points for model participants.

PCMA Recommendation: PCMA supports the CMS recommendation and looks forward to the results of the CMS analysis as to whether the various CMMI approaches significantly advantage or disadvantages plans participating in the CMS model tests.

e. Opioid Overuse (Part C)

CMS Proposal: For HEDIS, NCQA is collecting data on Use of Opioids at High Doses and Use of Opioids from Multiple Providers. CMS welcomes feedback about the value of including these Part C measures on the display page, given the similar Part D measures that constitute data for Patient Safety reports. CMS is interested in feedback as to whether and how MA contracts have a unique role, in contrast to stand-alone PDPs.

Discussion: With the importance of appropriate responses to the ongoing national opioid crisis, every accreditation body and measurement steward is prioritizing the development of quality

measures evaluating plans on their role in combatting the crisis by appropriately managing patients overusing opioids. PCMA is very supportive of this focus on opioids. However, we are concerned when the various measures adopted by CMS are similar but not identical to one another creating extra measurement burden without additional value in combating opioid overuse.

***PCMA Recommendation*: PCMA does not think there is any value to including this additional opioid measure on the display page. CMS should continue to focus its attention on the current PQA measures that accomplish the same purpose.**

f. Polypharmacy Measures (Part D)

CMS Proposal: Polypharmacy: Use of Multiple Anticholinergic (ACH) Medications in Older Adults – The percentage of individuals 65 or older with concurrent use of two or more unique ACH medications. CMS proposes to report the measure in the Patient Safety reports for 2018 measurement year. CMS plans to add the measure to the display page for 2021 and 2022 and consider this measure for the 2023 Star Ratings.

Discussion: This measure is duplicative as these drugs are included in the HRM measure. PCMA recommends that this measure not be added, as long as these drugs continue to be included in the HRM measure. If this measure is added, then ACH medications should be removed from the HRM list.

***PCMA Recommendation*: PCMA believes that this measure is duplicative as these drugs are included in the HRM measure.**

g. Polypharmacy: Use of Multiple CNS-Active Medications in Older Adults (Poly-CNS)

CMS Proposal: The percentage of individuals 65 or older with concurrent use of three or more unique CNS-active medications. (Must have two fills; beneficiaries in hospice are excluded). Lower rates = better performance. CMS proposes to report the measure in the Patient Safety reports for 2018 measurement year. CMS plans to add the measure to the display page for 2021 and 2022 and consider this measure for the 2023 Star Ratings.

Discussion: PCMA believes that this measure is duplicative as these drugs are included in the HRM measure. While the measure has clinical validity, it does not need to be used in addition to the HRM measure. If CMS proceeds to add this measure, CMS needs to ensure that the expectation is not that plans will reach zero as a percentage.

***PCMA Recommendation*: CMS should not add this measure, as long as these drugs continue to be included in the HRM measure.**

h. Concurrent Use of Opioids and Benzodiazepines

CMS Proposal: The percentage of individuals 18 years and older with concurrent use of opioids and benzodiazepines. CMS proposes to report the Concurrent Use of Benzodiazepines measure in the Patient Safety reports for 2018 measurement year. CMS plans to add the measure to the display page for 2021 and 2022 and consider this measure for the 2023 Star Ratings. CMS seeks feedback as to whether there are concerns with adding this measure because the OMS identifies potential opioid overutilizers who are also receiving benzodiazepines, and a proportion of the concurrent opioid and benzodiazepines users will already be identified within the Poly-CNS measure.

Discussion: As a stand-alone measure, PCMA would support the Concurrent Use of Opioids and Benzodiazepines measure. However, PCMA concurs with the concerns identified by CMS that the OMS identifies opioid overutilizers who are also receiving benzodiazepines and that some of the concurrent opioid and benzodiazepines users will be identified within the proposed Poly-CNS measure. CMS must be careful not to adopt multiple measures that assess the same information. In addition, as discussed in our comments above on this Draft Call Letter's opioid provisions, PCMA is concerned that the pending Part D NPRM limits what Part D plan sponsors can do to intervene with beneficiaries using benzodiazepines in addition to opioids. If CMS is to add the Concurrent Use of Opioids and Benzodiazepines in Patient Safety reports and/or as a display page measure, CMS must modify the limits on plan sponsor interventions as proposed in the NPRM. If CMS does not modify those provisions, it should not add the Concurrent Use of Opioids measure.

***PCMA Recommendation*: PCMA asserts that the Concurrent Use of Opioids and Benzodiazepines measure is not necessary and should not be added for the reasons CMS itself identifies as concerns. If CMS proceeds, it must modify the Part D NPRM proposal that limit what Part D plan sponsors can do to intervene with beneficiaries using benzodiazepines in addition to opioids. If CMS does not modify those provisions, it should not add the Concurrent Use of Opioids measure.**

i. Adherence to Non-Warfarin Oral Anticoagulants (ADH-NWOA)

CMS Proposal: Percentage of individuals 18 years and older who met the PDC threshold of 80 percent during the measurement period. CMS requests input on future use of the measure.

Discussion: PCMA has concerns with the ADH-NWOA measure, as it may not appropriately account for the full clinical picture, particularly if a beneficiary is non-adherent for clinical reasons. We are concerned that there may be a number of instances where the data does not capture these other clinical circumstances.

PCMA Recommendation: PCMA has concerns with the ADH-NWOA measure and recommends that CMS not add this measure to the display page at this time.

j. Adherence to Non-Infused Disease Modifying Agents Used to Treat MS (ADH-MS)

CMS Proposal: Percentage of individuals 18 years and older who met the PDC threshold of 80 percent during the measurement period. CMS requests input on future use of this measure.

Discussion: PCMA has concerns with the ADH-MS measure, as the measure may not appropriately account for the full clinical picture. We are concerned that there may be a number of instances where the data does not capture other clinical circumstances. Specifically, the integrity of the measure is reliant on integrated data, including pharmacy and medical claims, to truly measure whether a patient is following an appropriate drug therapy. In addition, for this therapeutic class, outcomes may not be evident for years after initiation of the selected drug therapy. New therapies may become available during the measurement period that are more appropriate for the beneficiary, and regular review of the most effective therapy for a beneficiary may be advantageous from both a quality of care and cost of care perspective. Patients and prescribers must have the flexibility to decide on the best regimen, depending on disease progression.

PCMA Recommendation: PCMA has concerns with the ADH-MS measure and as such, CMS should not add this measure to the display page at this time.

12. Measurement and Methodological Enhancements

a. "Topped Out" Measures

CMS Proposal: CMS will continue to analyze existing ratings measures to determine if measure scores are "topped out" or showing high performance across all contracts. In making decisions to transition such measures to the display page, CMS does not have a strict formula. CMS wants to balance how critical the measures are to improving patient care, the importance of not creating

incentives for a decline in performance after the measures transition out of the Star Ratings, and the availability of alternative related measures.

Discussion: We address the use of topped out measures, in the section above on Forecasting to 2020 and Beyond.

PCMA Recommendation: As discussed above, CMS should determine how it handles topped out measures based on the merit and benefit of the individual measure.

b. Development of New Measures

CMS Proposal: CMS points out that effective processing of Part D coverage determinations and redeterminations by Part D plan sponsors is a critical area of the Part D program. CMS indicates an interest in developing new or enhanced measures of beneficiary access. CMS is also interested in evaluating plan sponsors' compliance with effectuating appeals and provide outreach requirements, as well as appropriate clinical-decision making and notification to beneficiaries.

Discussion: As we have indicated previously, PCMA strongly opposes the inclusion of audit findings and enforcement actions within the Star Ratings program. Part D plan sponsors are audited to ensure that plans effectively process coverage determinations and redeterminations and for issues related to beneficiary access and notification. The Star Ratings measures should focus on quality of care, while audits can assess operational issues.

PCMA Recommendation: PCMA strongly opposes the inclusion of audit findings and enforcement actions within the Star Ratings program as well as the development of measures based on audit finding.

SECTION III: Part D

1. Validation Audits

CMS Proposal: CMS states that it welcomes comments on the process changes below regarding the threshold for requiring an independent validation audit:

- CMS currently requires sponsoring organizations that have more than five program audit conditions in their final audit report to hire an independent auditing firm to conduct a validation audit. CMS seeks comments on whether this threshold should be increased or decreased, or limited to conditions that may cause adverse impacts to beneficiaries.

- CMS intends to exclude Compliance Program Effectiveness (CPE) conditions from the threshold calculation as they do not directly and adversely impact beneficiaries.
- Sponsoring organizations with more than five non-CPE conditions cited in their final audit report will be required to hire an independent auditing firm. CMS will conduct the validation audits of sponsoring organizations that fall below this proposed threshold.

CMS clarifies that although it intends to exclude CPE conditions from the threshold calculation used in determining whether a sponsoring organization would be required to hire an independent auditing firm, the requirement to validate correction of CPE conditions would not be eliminated.

Discussion: PCMA appreciates the efforts by CMS to assess process changes for independent validation audits. In particular, we fully support the proposal to exclude CPE conditions from the threshold calculation as such conditions do not directly or adversely impact beneficiaries.

PCMA Recommendation: PCMA supports the changes proposed by CMS regarding the threshold for requiring an independent validation audit.

2. Required use of CMS Validation Audit Work Plan Template

CMS Proposal: CMS intends to create a validation work plan template that sponsoring organizations undergoing independent validation audits in 2019 would be required to submit. The draft template, which will be proposed in an upcoming Federal Register information collection, would include sections to capture the following information:

- A summary of the independent auditing firm's prior experience with Medicare Part C and Part D auditing, including examples of the experience.
- A summary of any Medicare-related work previously performed for the sponsoring organization by the independent auditing firm.
- Expectations for the timeframe of universe periods.
- Expectations for sampling cases for both universe integrity testing and to evaluate case compliance related to a specific condition.
- A requirement to attach the independent auditing firm's proposed audit report template.

Discussion: PCMA is supportive of the changes proposed by CMS, as they should result in a more streamlined validation audit process.

PCMA Recommendation: ***PCMA supports CMS's efforts to standardize the validation audit work plan template and appreciates the upcoming opportunity to comment on the specifics through the Paperwork Reduction Act process.***

3. Timeframe to Complete Validation Audits

CMS Proposal: CMS intends to give sponsoring organizations 180 days (an increase of 30 days from last year) from the date that CMS accepts their program audit CAPs to undergo a validation audit and submit the independent audit report to CMS for review.

Discussion: PCMA appreciates that CMS is proposing a change based on input from stakeholders who share their experience that the current time frame does not allow sufficient time to remediate issues and then validate that the actions were corrected. PCMA supports changes like this which are based on actual experience, and which provide plans more flexibility on timing to most appropriately validate audit findings.

PCMA Recommendation: ***PCMA supports the proposed extension of the time frame to complete validation audits to 180 days.***

4. Plan Finder Civil Money Penalty (CMP) Icon or Other Type of Notice

CMS Proposal: Starting with the 2019 AEP, CMS intends to display an icon or other type of notice on Plan Finder for sponsoring organizations that have received a CMP. CMS expects that the icon or notice would provide current and prospective enrollees with general information about a CMP, and may link to the CMP letter on the CMS website for that particular sponsoring organization. CMS proposes to begin displaying the CMP icon (or other type of notice) on Plan Finder for the 2019 AEP for any sponsoring organization that receives a CMP in 2018 (or receives a CMP for a 2017 Program Audit). Beginning in 2019, CMS proposes that regular updates would occur throughout the year.

Discussion: PCMA is very concerned with the CMS proposal to impose CMP icons on Plan Finder. While we support transparency, we do not believe use of a CMP icon is beneficiary friendly nor does it help achieve CMS's goal of providing enrollees with general information about a CMP. Instead, it will be confusing and create disparities between large plans and smaller plans, and between CMPs for major violations resulting in enrollment freezes, for example, as compared to CMPs for minor violations resulting in a fine, for example.[7] We also do not

[7] Indeed, in the CMS report for CMPs for 2016, one plan was fined only a little over $3,000. CMS Medicare Parts C and D Oversight and Enforcement Group. (May 9, 2017). *2016 Part C and Part D Program Audit and Enforcement Report*. Available at

understand what meaningful information this icon provides beneficiaries beyond the current icons for low-star rating and for inability of a plan to enroll new members. Indeed, we suggest that the considerations here for CMS are similar to how BAPP was handled for star ratings, where the agency removed from the BAPP measure all enforcement actions and reductions for plans under sanctions due to inconsistency of timing of audits and enforcement actions.

If CMS is to proceed with the CMP icon, the CMS proposal raises several questions that need to be addressed. These include:

- Does CMS plan to differentiate based on the severity of the infraction?
  - Will there be a financial threshold so that if the CMP is below a set amount, the icon will not be posted?
  - Will there be a distinction based on whether the CMP sanction was financial only, or whether it involves an enrollment/marketing freeze?
- For what time period will the CMP icons be posted?
- How will mid-year postings work? (e.g., for what time period will these postings be posted?)
- How will the CMP icon be explained to current and prospective enrollees?
  - Will CMS provide an explanation?
  - Will the plan be required or allowed to provide an explanation?

We further strongly oppose including a link to the notice imposing the CMP, as that content will be extremely difficult for beneficiaries to understand. We are not aware of any precedent for posting such detailed and technical content on links directly aimed at educating beneficiaries on a specific plan (as compared to links more generally available to the public).

We would be pleased to discuss with CMS whether there are more effective ways to impart CMP related information to beneficiaries. For example, CMS might establish a dedicated 800 number for beneficiaries to call if they have questions about a plan sponsor's compliance standing. Another alternative would be for CMS to post information on Plan Finder as to where beneficiaries can find online, a current list of plans with CMPs. Such a site could also provide education on what a CMP means and the different types of CMPs.

***PCMA Recommendation*: CMS should not to proceed with an icon or notice on Plan Finder for plans subject to a CMP. Such an icon will lead to beneficiary confusion and is unlikely to offer any clear benefits in the enrollment process. Given the diversity of reasons for which**

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https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2017ProgramAuditCMP22618.pdf

CMPs are issued, we believe such a metric is wholly inappropriate. The agency should consider other alternatives to address CMPs that would be more helpful to beneficiaries.

5. Audit of the Sponsoring Organization's Compliance Program Effectiveness (CPE)

CMS Proposal: CMS states that it has received multiple inquiries from stakeholders expressing the burden on sponsoring organizations when they have to perform their own internal CPE audit while also being responsive to a CMS program audit in the same year. CMS is considering allowing sponsoring organizations that have undergone a program audit to treat the program audit as meeting the annual compliance program audit requirement in 42 C.F.R. §§ 422.503(b)(4)(vi)(F), and 423.504(b)(4)(vi)(F) for one year from the date of the CMS program audit. CMS is seeking comment on this.

CMS also requests comments on how this will impact burden for sponsoring organizations undergoing a program audit. CMS believes that it will reduce burden on sponsoring organizations already undergoing a CMS program audit and will eliminate the duplication of effort.

Discussion: PCMA again appreciates that CMS is proposing a change based on input from sponsoring organizations who experienced burdens when performing their own internal CPE audit at the same time that they were responding to a CMS program audit. We concur with the CMS assessment that this change will reduce the burden on entities already undergoing a CMS audit and will eliminate duplication of effort.

PCMA Recommendation: PCMA supports the proposed changes to the CPE audit process as they will help make the audit process more efficient and reduce duplication of effort for both the sponsoring organization and the government.

6. New Medicare Card Project

CMS Proposal: CMS provides that beginning in April 2018, the current Social Security Number based HICN will be replaced with a new Medicare number, the Medicare Beneficiary Identifier (MBI). MBIs will be assigned to all Medicare recipients, and new Medicare cards will be mailed to beneficiaries beginning in April 2018. During the transition period (April 1, 2018 to December 31, 2019), Medicare plans can use either the HICN or the MBI to exchange data with CMS.

Discussion: PCMA appreciates the wide range of activities CMS is in the process of conducting to help facilitate the transition from the HICN to the MBI. That said, our PCMA members still have Part D specific issues with the transition (e.g., what happens when an enrollee receives a card this spring and thinks they have been switched out of their Part D plan?). Moreover, our preference continues to be that CMS establish a blackout period so that plans can convert data. Further, we reiterate the request we have made that CMS schedule a session with Part D stakeholders to review Part D specific issues.

PCMA Recommendation: PCMA continues to recommend that CMS schedule a session with Part D plan sponsors to review Part D specific questions and that it consider a blackout period so that plans can convert data.

7. CY 2019 Formulary Reference File (FRF) – Removal of Rarely Used Drugs

CMS Proposal: CMS states that it recognizes that the FRF has expanded and now includes several drugs for which utilization under Part D would be extremely rare. To that end, CMS is analyzing the Part D utilization of current FRF drugs and will be removing drugs from the FRF based on these results. CMS states that the removal from the FRF does not mean that the drug is not eligible for Part D coverage. The deletion of such drugs would be based on very infrequent utilization under Part D.

CMS will release a draft FRF that reflects these changes in February of 2018, and will provide Part D sponsors and other stakeholders the opportunity to comment on the FRF changes. A subsequent CY 2019 FRF will be published in March 2018.

Discussion: We agree with the concept that the FRF should be streamlined to remove drugs with very infrequent utilization under Part D. We appreciate the forthcoming opportunity to comment on these proposed changes. We also suggest that CMS make information publically available as to this change, so that, for example, pharmaceutical manufacturers do not think that the exclusion from the FRF means that the drug is no longer covered under Part D.

PCMA Recommendation: PCMA supports the effort to remove rarely used drugs from the FRF and looks forward to the opportunity to comment on the proposed changes.

8. CY 2019 Formulary Reference File – Timing of Update Window

CMS Proposal: The summer formulary update window allows for the certain formulary changes: 1) the addition of drugs that are new to the summer release of the FRF, and 2) the submission of negative changes on brand drugs, if an equivalent generic or therapeutically similar drug is added to the summer FRF. In 2017, for the 2018 plan year, the update window was held from July 27 to July 31. Since the summer update window is the final opportunity for plan sponsors to remove drugs from their formularies prior to the start of the plan year, CMS proposes to move this window later into the summer, with the goal being the inclusion of newly approved brands and generics that occur in July and into August. CMS states that it recognizes that Part D sponsors must finalize their formulary submissions for CY 2019 with enough time to meet printing deadlines. CMS seeks stakeholder comment regarding the optimal submission window that balances the opportunity for additional formulary substitution versus the need to finalize formulary documents for printing.

Discussion: PCMA appreciates that CMS continues its policy broadening the types of formulary changes that may be made during the summer formulary update window so that it may now include "therapeutically similar drugs." These formulary changes help protect patients from potentially unsafe drugs (as a result of new information on safety and effectiveness) as well as maximize consumer savings by maximizing generic drug use and promoting use of less expensive but equally effective drug alternatives. We further appreciate CMS's proposal to move the summer window as late as possible into the summer to include changes that occur into August and its recognition that a reasonable time frame for the summer update window needs to balance the opportunity for formulary changes with administrative considerations. Unfortunately, PCMA members have experienced that the current time frame (e.g., end of July) already is the latest possible in order for them to be able to finalize all administrative tasks needed for the Fall open enrollment, especially in light of the fact that it typically takes CMS about 30 days to review and approve the update. Thus, we are not sure that there is any more flexibility to move the date later. However, if CMS were able to commit to a shorter time period for review and approval (e.g., three weeks), then the window could be moved later into August. For example, plan sponsors and their PBMs could submit the formulary at the end of the first week in August, knowing they would receive approval before the end of the month.

PCMA Recommendation: ***PCMA appreciates the CMS proposal to move the summer formulary update window to later in the summer but can only support such a change if CMS can expedite approval of the summer formulary update.***

9. Changes for CY 2019 Formulary Submissions: Non-Extended Day Supply (NDS) File

CMS Proposal: CMS states that it has concluded that the burden of maintaining the supplemental NDS File outweighs any benefit. Thus, CMS is eliminating this supplemental file for CY 2019. Part D sponsors will continue to identify in the plan benefit package (PBP) if there are any drugs for which the plan imposes a limit of a one month supply, if the drugs are included on a tier that is otherwise available at an extended day supply.

Discussion: PCMA agrees with CMS that the burden of maintaining the NDS File outweighs the benefit. PCMA appreciates the efforts by the Agency to identify and eliminate files where the burdens outweigh the benefits (if any).

PCMA Recommendation: PCMA supports the proposal by CMS to eliminate the NDS File.

10. Changes for CY 2019 Formulary Submissions: Over-the-Counter (OTC)Validation File

CMS Proposal: In an effort to reduce the burden on Part D sponsors to create and submit these files, and to streamline the CMS review of the OTC submissions, CMS is proposing to provide plans with an OTC reference file for CY 2019 that uses a proxy code (e.g., RXCUI) to represent each unique drug ingredient, strength, route, and dosage form, but the file will not contain every possible branded OTC. CMS will provide Part D sponsors an opportunity to review a draft OTC reference file well in advance of the supplemental file submission deadline.

Discussion: PCMA appreciates the proposal to reduce the burdens involved with the submission of the OTC Validation File. PCMA looks forward to the opportunity for it and its members to review a draft.

PCMA Recommendation: PCMA agrees with the CMS proposal to provide plans with an OTC reference file for CY2019 that uses a proxy code but does not necessarily contain every possible branded OTC.

11. Expanding the Part D OTC Program

CMS Proposal: CMS is contemplating allowing additional flexibilities for Part D plan sponsors to offer access to OTCs. For example, CMS could consider allowing sponsors to include additional OTC products such as dietary supplements and cough medicines, without the requirement that the OTC product offset the use of a Part D drug. CMS recognizes that any such

expansion of the current policy could potentially increase program costs and reminds plan sponsors that the beneficiary inducement laws still apply. CMS solicits feedback from stakeholders on Part D OTC enhancements that could be considered for future policy. This feedback could include information on how well the current program is working, the deficiencies of the current program, what additional flexibilities would be helpful, and what the impact would be on spending, particularly premiums, as a result.

Discussion: As CMS is aware, the Part D statute prohibits coverage of OTCs except in very limited situations – and current law may not permit such coverage to be funded with anything other than administrative dollars. See Section 1860D-2(e)(2)(A). Thus, we are not sure that the Draft Call Letter is the appropriate vehicle to consider potential changes.

PCMA Recommendation: Instead of using the Draft Call Letter as the vehicle to consider potential changes to Part D OTC, PCMA suggests that CMS consider obtaining feedback on coverage of OTC under Part D through an RFI process, and/or through a CMMI initiative.

12. Part D Benefit Parameters for Non-Defined Standard Plans

CMS Proposal: CMS states that specific guidance related to the EA to EA PDP meaningful difference will be included as part of the Final Rule. For CY 2019, CMS intends to follow the same methodology that was utilized to determine the CY 2017 and CY 2018 basic to enhanced meaningful difference threshold. CMS proposes a minimum monthly cost-sharing out-of-pocket-costs (OOPC) difference between basic to enhanced PDP offerings of $22 (up $2 from last year).

Discussion: As we noted in our comments to the EA to EA proposal in the Part D NPRM, PCMA supports eliminating the requirement to provide PDP EA-to-EA plan offerings with meaningful differences. We concur that this change will help to balance the Agency's goals of increasing competition and plan flexibility while still affording beneficiaries with meaningfully different choices in Part D benefit packages.

Further, we appreciate that CMS is contemplating eliminating the meaningful difference between basic and EA plans. As CMS deliberates this option, we reiterate that CMS should take into account that this test may stifle innovation, reduce consumer choice, and impose additional costs on plans. While in the 2018 Call Letter, CMS lowered the OOPC differential between basic and enhanced PDP offerings, the OOPC difference between basic and EA PDP offerings is still too high, which may make enhanced plans very expensive and out of reach for many beneficiaries, further limiting consumer choice.

With respect to the Draft Call Letter, and in order to maintain consumer choice and prevent beneficiary disruption, PCMA continues to urge CMS to lower the OOPC differential between basic and enhanced PDP offerings. We believe the proposed $22 OOPC difference between these offerings is too high. The agency does not provide any actuarial or other analytics to support this decision, and thus, it appears to be arbitrary. Moreover, the proposed $22 OOPC differential not only ignores some of the most important beneficiary considerations in selecting a plan, such as formulary, pharmacy network, and cost-sharing amounts, but also relies on a misplaced assumption that beneficiaries prefer fewer, not more, options. Consistent with how beneficiaries select plans, CMS should lower the OOPC differential between basic and enhanced PDP offerings back to the $20 in place for 2018. We also urge CMS to create a consistent OOPC differential between basic and EA plans that does not change from year to year. This would provide plan sponsors with more predictability and reduce unnecessary changes, while still assuring that enrollees receive meaningful value.

As justification for this proposal, CMS continues to cite the closing of the coverage gap as we near CY 2020. As PCMA noted in its comments to the CY 2018 Call Letter, there is no evidence that Congress, in reducing the coverage gap, also intended to limit the range of plan offerings in the market. Indeed, Congress, in enacting the Bipartisan Budget Act of 2018 (the BBA), just moved up the closing to 2019, and did not make any other changes to the benefit[8]. Furthermore, CMS already has authority to address the problems of low enrollment plans or enhanced plans that are perceived to be of low value by beneficiaries, and does not need to reduce the number of plans that a PDP can offer, to no more than two per region.

PCMA Recommendation*: *CMS should lower the proposed OOPC differential for 2019 to $20 (which is the current 2018 amount) from the proposed $22 amount. CMS should also create a consistent OOPC differential between basic and enhanced PDP offerings that does not change from year to year.

13. Tier Composition

CMS Proposal: Based on an analysis of CY 2018 formulary and benefits data, CMS proposes a maximum threshold of 25% generic composition for the non-preferred brand tier for CY 2019. CMS continues to believe a coinsurance structure is the preferable cost-sharing structure for the non-preferred drug tier. CMS intends to conduct outlier tests for those Part D sponsors who choose a copay structure for the non-preferred drug tier.

[8] In the last section of these comments, we note topics from the BBA on which additional guidance from CMS would be appreciated.

Discussion: We do not understand what problem CMS seeks to solve by reducing the maximum generic composition for the non-preferred brand tier from 50% to 25%. PCMA is concerned with the potential adverse unintended consequences if CMS reduces the generic threshold in the non-preferred tier to 25%. We offer the following example to illustrate possible adverse implications. As CMS is aware, some plans using the standard formulary tier have copays rather than coinsurance for that tier. We understand from a member's formulary expert that the placement of High Risk Medication (HRM) drugs alone in the non-preferred tier will result in a generic percentage close to 25%, making it extremely problematic to place any other generics in that tier. In this instance, the only other option for the plan is to place the HRM drugs on a lower tier, which then increases the likelihood of increased but avoidable usage of HRM drugs.

Our PBM members further inform us that they are seeing an increase in the number of prescriptions for expensive generics. In light of the unintended consequences and the dramatic change in generic pricing, we request that CMS perform further analysis (using multiple years of data) before proceeding with this change.

PCMA Recommendation: ***PCMA does not support the proposed change to reduce the maximum threshold of generic composition for the non-preferred brand tier from 50% to 25%. Instead, CMS should retain the current 50% threshold as it allows plans appropriate flexibility in formulary tier placement.***

14. Benefit Parameters for Non-Defined Standard Plans

CMS Proposal: CMS retains the maximum copay and coinsurance threshold values for all tiers for the fourth year in a row.

Discussion: As PCMA has noted for the last few years, without an inflationary adjustment for brand and non-preferred drug tiers, Part D plan sponsors will be forced to adjust benefits in a way that reduces value for the majority of beneficiaries. Not allowing an increase in the maximum copay and coinsurance thresholds for brands, paired with increased brand-name medication costs, effectively results in a significant year-over-year benefit enhancement, which will lead to increased premiums for all beneficiaries while only benefiting beneficiaries that take expensive brand drugs.

PCMA Recommendation**: *PCMA once again recommends CMS make an inflationary adjustment for cost-shares for preferred brand, non-preferred brand and non-preferred drug tiers for 2019 and annually thereafter.***

15. Improving Drug Utilization Review Controls in Medicare Part D

Overview: PCMA and its members are committed to working with CMS to address the opioid epidemic and we commend the Agency for its ongoing dedication to this crisis. In general, we are encouraged that CMS is proposing a number of steps to allow Part D plan sponsors to take more action to prevent over-prescribing of prescription opioids. Specifically, in alignment with CDC Guidelines for Prescribing Opioids (CDC Guidelines), [9] we support initial prescriptions being limited to a 7-day supply.

Furthermore, PCMA members support the implementation of Comprehensive Addiction and Recovery Act of 2016 (CARA) and the adoption in Part D of a lock-in mechanism as a means to curtail inappropriate abuse of certain medications by certain Part D enrollees. As noted in our comments on the 2019 Part D NPRM, we appreciate CMS's proposal to integrate the CARA drug management provisions with the current Part D Opioid DUR policy and the Overutilization Monitoring System (OMS). As CMS finalizes its drug management policies as proposed in both the NPRM and the Draft Call Letter, we urge the Agency to consider the interactions of the content of the two issuances to ensure that guidance is structured in a way that is consistent and streamlined.

We want to emphasize that addressing the opioid epidemic requires coordination across a multitude of entities and agencies and we thank CMS for its leadership in this arena. As efforts progress, we urge the Agency to harmonize the wide range of initiatives aimed at curtailing opioid overutilization. Our more detailed comments are set forth below.

a. Retrospective DUR

i. CARA and OMS

CMS Proposal: CMS is now in the process of considering comments from the public on the 2019 Part D NPRM, which proposed to codify the Part D retrospective opioid overutilization policy, OMS reporting and related provisions to implement CARA.

Discussion: The implementation of CARA and the adoption in Part D of a lock-in mechanism will provide Part D plan sponsors with an important tool to help limit inappropriate abuse of opioids and other medications. In our comments on the 2019 Part D NPRM, PCMA made a

[9] CDC Guideline for Prescribing Opioids — United States, 2016 Found at: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm (March 15, 2016).

number of recommendations to enhance beneficiary safety and effective implementation of the drug management program. First, CMS should permit Part D plan sponsors greater flexibility and discretion in implementing their programs. Second, Part D plan sponsors should be able to implement the lock-in restrictions prior to the proposed six-month delay. Third, CMS should incorporate the CARA drug management provisions into existing requirements carefully to promote movement toward a more integrated and seamless system of care.

As noted above, as CMS finalizes the 2019 Part D NPRM and the Draft Call Letter, we urge the Agency to ensure that the policies put forth are consistent. If these activities are not coordinated, the result may be conflicting guidance. It will be important for Part D plan sponsors, their PBMs, and any other relevant stakeholders to understand how the CARA lock-in requirements will interact and coordinate with the current DUR policy and OMS.

***PCMA Recommendation*: CMS should finalize all opioid-related policy in an efficient and consistent manner. CMS should also provide Part D plan sponsors greater flexibility and discretion in implementing their drug management programs.**

ii. OMS Metrics

CMS Proposal: Beginning with the 2018 OMS reports, CMS proposes to change the Opioid Daily Dose measurement period from 12 months to 6 months to align with the revised OMS criteria measurement period. In addition, CMS proposes to report a second Opioid Daily Dose rate with a 90 MME threshold to further align with the revised 2018 OMS criteria. CMS also would discontinue reporting the 120 MME Opioid Daily Dose rate in the 2019 OMS reports.

Discussion: PCMA supports reducing the measurement period to 6 months, which makes the data much more relevant, since the longer period often captures situations that have already been resolved. We also agree that the second Opioid Daily Dose rate with a 90 MME threshold will further align with the revised 2018 OMS criteria. Additionally, we support discontinuing the reporting of the 120 MME Opioid Daily Dose report as it is no longer consistent with the OMS MME threshold and the CDC Guidelines.

Though not specifically raised in the Draft Call Letter, we think it is important to address CMS's recently released updated Opioid Oral MME Conversion Factors in this section as it is a pertinent component in improving retrospective DUR programs. In, the MME Conversion Factors, Buprenorphine products are listed, but do not have an associated MME conversion factor. CMS states that, "these buprenorphine products, as partial opioid agonists, are not

expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids."[10]

Buprenorphine products are indicated for both medication-assisted treatment (MAT) and management of pain, and it is critical for CMS to distinguish between the two indications. While we understand why buprenorphine products indicated for MAT should not be used to benchmark against dosage thresholds meant for opioids prescribed for pain, we are confused as to why CMS has not included a MME conversion factor for the two buprenorphine products (e.g. Belbuca and Beltrans), that are indicated only for the management of pain. This is particularly puzzling in light of the black-box safety labeling warning for buprenorphine patches (e.g. Beltran), which has been linked to a risk for misuse, abuse, and diversion.[11]

To add to the confusion, CMS in its recent Drug Trend Analytics Report, recommended that Part D plan sponsors monitor the utilization of Belbuca and Beltran for medical necessity, given the risks of abuse.

***PCMA Recommendation*: PCMA supports the proposed changes to the OMS metrics. In light of buprenorphine products not having an associated MME conversion factor, CMS should clarify whether plan sponsors should include, in their OMS program, Buprenorphine products that are indicated for pain only.**

iii. Opioid Potentiator Drugs

CMS Proposal: CMS proposes to add a concurrent opioid-gabapentin/pregabalin flag to OMS. CMS also seeks comment on other potentiator drugs that should be added to the OMS and the utility of adding such drugs that may increase the risk for overdose when used with opioids.

Discussion: To enhance beneficiary safety, we agree that CMS should add a concurrent opioid-gabapentin and pregabalin flag to OMS. PCMA members have noted that these and other highly abused drugs, such as benzodiazepines and centrally acting muscle relaxants, are commonly used in combination with opioids and may contribute to abuse and misuse. According to a recent article in the New England Journal of Medicine, despite the trend of increasing benzodiazepine overdoses, the adverse effects of its overuse, misuse, and addiction continue to go largely unnoticed.[12]

[10] Opioid Oral MME Conversion Factors. Found at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-vFeb-2018.pdf
[11] Butrans (buprenorphine transdermal system). Found at https://butrans.com/
[12] NEJM. Our Other Prescription Drug Problem. Found at: http://www.nejm.org/doi/full/10.1056/NEJMp1715050.

In light of evidence, including the Agency's own research, which has identified benzodiazepines as a significant health threat to Medicare beneficiaries,[13] we recommend that CMS also expand the frequently abused drugs definition to include these drugs for the CARA lock-in program as well. Limiting the reviews to opioids only for both the OMS beneficiary-specific POS edits as well as the lock-in function, may have the unintended consequence of driving potentially at-risk or at-risk individuals towards the use of other highly abused potentiator drugs and limiting the Part D plan sponsor's ability to manage all potentially abused or misused controlled substances. While opioids are the focus of many initiatives, we believe that it is important to review and manage all of the highly abused drugs a beneficiary may be taking in order to reduce the risk of inappropriate drug use.

Finally, this is an area in particular where CMS needs to ensure alignment with the 2019 Part D NPRM, in which CMS (in contrast) proposes to designate only opioids as frequently abused drugs.

***PCMA Recommendation*: PCMA supports the proposal for CMS to add a concurrent opioid-gabapentin and pregabalin flag to OMS, along with a similar flag for centrally acting muscle relaxants. CMS should also incorporate the expansion to other potentiator drugs in the final rules for CARA lock-in program, including CNS sedatives such as carisoprodol and non-BDZ sleeping medications (e.g., zolpidem, zaleplon, and eszopiclone).**

iv. Patient Safety Reporting

CMS Proposal: CMS states that sponsors may use the Patient Safety reports to supplement their DUR programs to address overutilization of opioids across a population broader than OMS. CMS also expects sponsors to monitor these data to compare their performance to overall averages.

Discussion: We appreciate the statement that Part D plan sponsors may use the Patient Safety reports to supplement their DUR programs. Part D plan sponsors already routinely monitor Patient Safety reports when assessing their progress in reducing the number of beneficiaries using high doses of opioids. Thus, we request that guidance does not further mandate the use of these reports. Further, as indicated in the section of our comments above on Future Measurements, CMS should not add the Concurrent Use of Opioids and Benzodiazepines measure to the Patient Safety reports for reasons CMS itself identifies as concerns.

[13] CMS. Concurrent Use of Opioids and Benzodiazepines in a Medicare Part D Population. Found at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Concurrent-Use-of-Opioids-and-Benzodiazepines-in-a-Medicare-Part-D-Population-CY-2015.pdf

***PCMA Recommendation*: CMS should not mandate Part D plan sponsors to use Patient Safety reports when assessing their progress in reducing the number of beneficiaries using high doses of opioids, with or without multiple providers and pharmacies.**

b. Concurrent DUR

i. Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users

CMS Proposal:

- CMS proposes that all sponsors should implement a hard edit in 2019 that is triggered when a beneficiary's cumulative daily MME reaches or exceeds 90 mg (meaning the MME threshold should only be set at 90 MME).

- Sponsors should not include multiple prescriber or multiple pharmacy criteria in these edits so that all beneficiaries using 90 MME per day or more regardless of the number of providers are identified.

- CMS proposes that sponsors should allow beneficiaries to receive a 7 days' supply of the prescription that triggered the 90 MME hard edit.

- CMS requests comment on this concept and stakeholder feedback on its operational feasibility.

- CMS asks if it should finalize a policy whereby the 7 days' supply is available only once after the 90 MME hard edit is triggered during a specific time period, if a patient presents at the pharmacy with multiple opioid prescriptions on the same day, if only one 7 days' supply was allowed, the pharmacist would assess the immediate needs of the patient to help determine which prescription should be filled for a 7 days' supply.

- CMS further seeks comment on when and how to best communicate to beneficiaries that the one-time 7 days' supply would not be available for future prescriptions should the MME level remain at 90 mg or higher.

- CMS seeks feedback on whether all sponsors have the capacity to implement hard edits at 90 MME as well as the 7 days' allowance proposal for 2019.

Discussion: PCMA agrees with the CDC Guidelines that "when opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed."[14]

In alignment with these guidelines, we are encouraged that CMS is proposing a number of steps to limit the supply of prescription opioids to 7-days. However, while case management and POS edits may reduce inappropriate levels of opioid utilization, these efforts alone will not fully address the opioid epidemic. CMS must also consider a multifaceted approach to this crisis, which takes into account the role of prescribers and the need for training and tools to help ensure appropriate prescribing behaviors. For example, policies that promote the use of electronic prescribing can, among other things, help to ensure that opioid prescribing for acute pain is limited at least initially to a 7-day supply.

Our comments seek to provide input on the overall approach as put forth by CMS, as well as outline several considerations that CMS should address to help operationalize and ensure the success of its proposal.[15] Please note that the issues outlined below also apply to the proposal related to days' supply limits for opioid naïve patients.

1. **System Changes and Timeline**. While most Part D plan sponsors have the capacity to implement hard edits at 90 MME, integrating the MME edit with the 7-day supply limit at the POS requires system modifications, coding changes and enhancements. We are concerned that Part D plan sponsors may not have the necessary system changes in place by January 1, 2019. For example, Part D plans will need to develop system changes to enable a patient to receive a 7-days' supply day of opioids until the exception request is approved whereby the patient obtains the remaining fill. Part D plan sponsors also need guidance on how to account for pro-rated drug cost-sharing and dispensing fees when a single opioid prescription is separated into two prescriptions.

   PCMA Recommendation: Given the complexities and the number of logistical and operational issues that need to be addressed, along with the high number of beneficiaries expected to be impacted, CMS should permit plans greater flexibility in implementing their programs. As part of this flexibility, CMS should give plan sponsors the option to utilize soft edits to manage the de-escalation of opioid dosages >50mg - 200mg MME for chronic users of opioids. In addition, CMS should provide

[14] CDC Guideline for Prescribing Opioids — United States, 2016 Found at: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm (March 15, 2016).
[15] In this section, we include our recommendations as part of each point.

that hard edits are used for opioid dosages > 200mg MME. This approach would allow for a smoother implementation process in 2019. PCMA also notes that implementation of the proposal could involve significant changes and updates to systems and processes to address issues like identifying and processing exemptions from the 7-day limit (e.g., for people with cancer diagnoses). CMS should therefore ensure that plan sponsors have enough lead time to design and implement such requirements.

2. **Interaction with State Laws**. Some states require patients to fill a prescription for a Schedule II drug within a certain amount of time (e.g. 7 days) after the date of issue on the prescription order. This may necessitate the patient returning to the prescriber for an additional prescription. Furthermore, some states may not allow beneficiaries to "partially" fill a Schedule II drug.

   PCMA Recommendation: CMS should coordinate with other federal and state entities (e.g., DEA and State Boards of Pharmacy) to ensure that CMS policies combined with state regulations are aligned and not in conflict. CMS should also consider preempting conflicting state laws where appropriate.

3. **Interaction with Transition Fill Requirements**. Part D plan sponsors are required to provide for an appropriate transition process for certain enrollees who are prescribed Part D drugs that are non-formulary. In the retail setting, the transition fill of non-formulary Part D drugs must be for at least 30 days, unless the prescription is written by a prescriber for less than 30 days. Part D plan sponsors need to understand how to treat the opioid 7-days' supply if the drug is also eligible for a transition fill. Plans also need clarity as to whether the 7 days' supply prescription is considered a single prescription or a partial fill.

   PCMA Recommendation: CMS should clarify in its guidance, including updates to Chapter 6,[16] that all days' supply limits take precedence over transition fill requirements. In any event, CMS should not allow the inappropriate use of opioids during the enrollee's transition period.

4. **Pharmacy and Therapeutics (P&T) Committee**. The CDC Guidelines are an important tool for prescribers which help to inform appropriate decision-making. We also understand that individual patient needs may vary and that using a one-size-fits-all approach in determining potentially inappropriate levels of opioid utilization may not take into account special circumstances.

[16] All Chapter cites are to the Medicare Prescription Drug Manual available at https://www.cms.gov/medicare/prescription-drugcoverage/prescriptiondrugcovcontra/partdmanuals.html

***PCMA Recommendation*: CMS should not establish policies that prevent appropriate clinical input from P&T committees.**

5. **Utilization Management (UM) Edit Versus Safety Edit**. Part D plan sponsors and their PBMs need to understand whether CMS considers a 7-day supply limit to be a UM edit that requires submission and approval by CMS under 30.2.2.1of Chapter 6 of the Prescription Drug Manual or a safety edit that does not require submission and approval from CMS under 30.2.2.2. Likewise, clarity on whether the 7-day supply limit is a safety edit or an UM edit will dictate whether it requires a coverage determination to determine appropriate use. Given the express purpose of reducing opioid abuse and misuse, we believe the 7-day limit is more appropriately classified as a safety edit.

   ***PCMA Recommendation*: CMS should clarify in its guidance, including updates to Chapter 6, that opioid days' supply limits are considered safety edits and do not require coverage determinations or prior CMS approval.**

6. **CMS Submission and Approval**. CMS considers safety edits that prevent dispensing of unsafe dosing of drugs to be part of the concurrent DUR requirements for all Part D drugs. CMS does not require Part D sponsors to submit POS safety related edits as part of their HPMS formulary submission, even if they are implemented as hard edits (with the exception of opioid specific edits, as defined in section 30.2.2.1).

   ***PCMA Recommendation*: CMS should clarify that all days' supply limits for opioids are considered safety edits and are not part of the HPMS Formulary submission process.**

7. **Quantity Limit Versus Opioid Specific Safety Edit**. In certain cases (and subject to CMS approval) a Part D plan sponsor may apply a hard quantity edit for certain individual patients for certain opioids. In such a case, any transition supply is generally not available.

   ***PCMA Recommendation*: CMS should clarify in its guidance, including updates to Chapter 6, that the 7 days' supply limit applies only when a plan implements a hard safety edit for a beneficiary exceeding 90 MME per day or more of opioids, and not when a plan implements a hard quantity edit that may be set at a different MME, or for any beneficiary-specific POS overutilization edits.**

8. **Guidelines for Tapering Opioids**. We are concerned that CMS's proposal uniformly places a 90mg MME hard edit on all beneficiaries regardless of the duration of their

opioid treatment and without regard for tapering opioids as noted in the CDC Guidelines and further elaborated in the CDC's Companion Guidelines for Tapering Opioids for Chronic Pain (CDC Tapering Guidelines), which may lead to adverse clinical outcomes, such as withdrawals.[17] According to the CDC Tapering Guidelines, prescribers should follow up regularly with patients that are being treated with opioids longer than 3 months to determine whether opioids are meeting treatment goals and whether opioids can be reduced to lower dosage or discontinued. The guidelines advise that opioid tapering plans should be individualized and should minimize symptoms of opioid withdrawal while maximizing pain treatment with nonpharmacological therapies and non-opioid medications. The guidelines also state that a reasonable starting point for an opioid tapering plan is generally a decrease of 10% of the original dose per week. The guidelines note that some patients who have taken opioids for a long time might find even slower tapers (e.g., 10% per month) easier.

Subjecting all chronic users of opioids to a 90mg MME hard edit—along with the plan requirement to approve exception requests for these hard edits for the remainder of the plan year—is clinically inappropriate and disconnected from the CDC Tapering Guidelines which stipulate a 10% reduction in the dose per week or month- depending on the duration of opioid treatment. The policy as proposed will not reduce a beneficiary's exposure to chronic high MME opioid doses in a manner that is consistent with the CDC Tapering Guidelines. Furthermore, we are concerned that beneficiaries will be immediately subjected to a lowering of the MME to <90mg through the exceptions process without opportunity for the plan to engage with and educate prescribers on the calculation of MME and to facilitate tapering the opioid dosage consistent with the guidelines.

Conversely, approving the exception request for the existing >90mg MME level triggered by the hard edit—which, if approved, is required to remain for the remainder of the plan year--provides no opportunity for the plan to engage with the prescriber to manage opioid tapering outlined in the guidelines. In other words, exception requests for greater than 90mg MME would be approved for the remainder of the plan year based on a point in time assessment without any incentive for the prescriber and member to collaborate and engage in an opioid tapering plan. Neither scenario facilitates a reduction in a beneficiary's exposure to high doses of opioids consistent with the CDC Tapering Guidelines.

[17] Pocket Guide: Tapering Opioids For Chronic Pain. https://www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf

PCMA Recommendation**: 1) As an alternative to the use of the 90mg MME hard edit for high MME and chronic opioid utilizers, CMS should permit plan sponsors to utilize soft edits to manage the de-escalation of opioid dosages >50mg - 200mg MME for chronic users of opioids, which aligns with the CDC Tapering Guidelines; 2) CMS should provide that hard edits be used for opioid dosages > 200mg MME; 3) CMS should develop a model Opioid Tapering Notice based on the CDC Tapering Guidelines that would be provided to the beneficiary at the pharmacy counter when a soft edit is triggered for a fill that exceeds >90mg MME informing them that after 90 days, a fill of greater than 75% of the current MME will reject for payment and require medical necessity review through the exception process; 4) CMS should require that any exception request related to the Opioid Tapering Notice be in writing from the prescriber with an attestation of medical necessity; and 5) Finally, CMS should permit plans to approve the exceptions associated with the Opioid Tapering Notice for up to 6 months, which would allow prescribers to initiate an opioid tapering plan to reduce the opioid MME exposure over time consistent with the CDC Tapering Guidelines.

9. **Supplemental Formulary File Submissions**. The supplemental formulary files require Part D plan sponsors to indicate which drugs are not available as an extended day supply. Some Part D plan sponsors include all opioids on the non-extended day supply supplemental formulary file. It is unclear whether the inclusion of a drug on the non-extended days' supply supplemental formulary file allows a plan sponsor to limit the day supply to 7 days for opioids in acute pain management.

   ***PCMA Recommendation**: CMS should clarify that the inclusion of a drug on the non-extended days' supply supplemental formulary file does not restrict a Part D plan sponsor's ability to limit the day supply to 7 days for opioids in acute pain management. CMS should also clarify the processes that a Part D plan sponsor must undergo to make timely changes to the non-extended day supply formulary file if the plan wants to limit opioids used for acute pain to a 7 days' supply.*

10. **Coverage Determination**. CMS states that an enrollee, the enrollee's representative, or the enrollee's prescriber has the right to request a coverage determination for a drug or drugs subject to the MME edit. CMS also states that it generally expects coverage determination requests seeking exceptions to the MME edit to meet the criteria for expedited review.

    ***PCMA Recommendation**: CMS should clarify in its guidance, including updates to Chapter 6, that opioid days' supply limits are considered safety edits and do not require coverage determinations. If coverage determinations are required, CMS permit Part D*

plan sponsors to extend the tolling of the exception request time frame greater than 24 hours beyond the usual turnaround time to give plan sponsors time to obtain the needed information from the prescriber. This would also be in the beneficiary's best interest, as it would reduce the risk of denying coverage determination requests due to lack of information from the prescriber, particularly when the request is impacted by a weekend or holiday.

11. **Member Complaints**. Beneficiaries will likely experience disruption due to these changes, which will increase call center volume and specifically, complaints. We also have concerns about the potential impacts of the 7-days' supply limit and other drug management provisions may have on Part D program requirements such as Star Ratings and the handling and reporting of complaints/appeals.

    PCMA Recommendation: CMS should clarify that complaints about the 7-days' supply limits and other mandatory aspects of their drug management program will not be counted towards a Part D plan's quality ratings.

12. **Member and Prescriber Communication**. Part D plan sponsors need clear guidance from CMS on how to communicate the days' supply limit on formulary and other beneficiary documents. We are concerned that this policy will generate extreme amounts of member confusion, complaints, and inquiries to PBM call centers. Likewise, this policy change will also necessitate communication from CMS to prescribers explaining the changes and how they will work and how they should communicate with their patients.

    PCMA Recommendation: CMS should provide standard language for plan sponsors to include in their Annual Notice of Change and Evidence of Coverage documents. CMS should also fund and collaborate with interested stakeholders to design and implement a wide-reaching, public health service announcement campaign to promote and provide awareness around appropriate opioid prescribing guidelines.

13. **Quantity Prescribed Field**. As we have noted many times, PCMA is concerned with the number of RAC audit findings regarding refills on controlled substances, which threaten appropriate beneficiary access to controlled substances. RAC audits have systematically misidentified multiple "partial fills" as multiple refills, and flagged these transactions for review. This misidentification is a direct result of CMS's failure to adopt the 'Quantity Prescribed' (460-ET) field in the National Council for Prescription Drug Programs (NCPDP) format. Immediate availability of this field would permit appropriate claims editing, ensuring beneficiary access while reducing the administrative burden on the part

of Part D plan sponsors and PBMs – as well as RACs – in conducting retrospective reviews of these claims. We are not aware of any barrier to CMS proceeding with this initiative.

***PCMA Recommendation*: CMS must take all steps to immediately adopt the NCPDP proposed 'Quantity Prescribed' field.**

14. **Mid-Year Formulary Changes.** If CMS considers adopting the 7-day supply limit on opioids for acute pain UM under 30.2.2.1, Part D plan sponsors need to understand the proper mechanism to submit the formulary change. Part D plan sponsors also need to know whether CMS considers these changes to be a maintenance change or a non-maintenance change as defined in 30.3.3.

    ***PCMA Recommendation*: CMS should issue guidance that will deem approved all Part D plan sponsor changes that are undertaken to reflect consistency with the CDC Guidelines.**

15. **Multiple Opioid Prescriptions**. Should CMS finalize a policy whereby the 7 days' supply is available only once after the 90 MME hard edit is triggered during a specific time period, we ask CMS to clarify that if a patient presents at the pharmacy with multiple prescriptions for different opioids on the same day, the patient would receive a 7 days' supply of each prescription. Different opioids have unique pharmacological characteristics and properties which need to be accounted for. We do not believe it is the role of the pharmacist to determine which prescription should be filled for a 7 days' supply.

    ***PCMA Recommendation*: CMS should provide that if a patient presents at the pharmacy with multiple prescriptions for different opioids on the same day, the patient would receive a 7 days' supply of each prescription.**

16. **Cash Payment**. Part D plan sponsors would like to understand what CMS's expectations are for when a patient pays cash for a prescription opioid. Part D plan sponsors do not have the ability to apply edits after a patient receives their prescription drugs through cash payments.

    ***PCMA Recommendation*: Because Part D plan sponsors have no ability to influence a beneficiary's actions when the beneficiary chooses to obtain a prescription as a cash transaction, CMS should not hold Part D plan sponsors accountable when a beneficiary obtains an opioid without using their Part D prescription drug benefit.**

ii. Days' Supply Limits for Opioid Naïve Patients

CMS Proposal: CMS states that it expects all Part D sponsors to implement a hard safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain. CMS also requests feedback on the implementation of a days' supply limitation at 7 days and whether a days' supply limit with or without a daily dose maximum (e.g., 50 MME per day) would be more effective.

Discussion: As noted above, PCMA supports the CDC Guidelines, which align with the proposal of a days' supply limitation for initial prescription opioids. We believe that a 7 days' supply limit without a daily dose maximum would be most effective at minimizing the risk of opioid dependence.

In addition to the barriers noted above that CMS will need to address to implement a 7-day supply limit for the use of opioids in acute pain management, we also have the following concerns:

1. **Initial Prescription**. While a 7-day supply limit for initial prescription opioids is consistent with many new state requirements, it is typically incumbent on the dispensing pharmacy to discern whether the patient's opioid prescription is for an initial treatment of acute pain. However, under the proposed protocols, this responsibility lies with the Part D plan sponsor. It is unclear how Part D plan sponsors are expected to know whether an opioid prescription is for an initial treatment of acute pain at POS, particularly if the patient is a new enrollee with no prior claims history.

   PCMA Recommendation: ***PCMA supports the quantity limitation; however, CMS should consider options that move the conversation from a situation where patients are told "your Part D plan does not cover this medication" to interventions that move the conversation back to between the prescriber and the patient. If CMS does move forward with the 7-day supply hard edit, CMS should actively communicate to all beneficiaries that this is a Part D benefit change and that beneficiaries should expect this edit if they attempt to fill initial prescriptions for greater than 7 days. CMS should also make beneficiaries aware that a plan could inadvertently misconstrue a prescription as an initial prescription when a beneficiary is a new enrollee in a Part D plan.***

2. **Definition of Initial Prescription and Opioid Naïve Patients**. It is unclear what constitutes an "initial opioid prescription fill" or what the lookback timeframe should be

to make this determination. Similarly, it is unclear what is meant to be an opioid naïve patient. As noted above, Part D plan sponsors and their PBMs rely on P&T committees to develop clinical criteria for their drug management programs.

***PCMA Recommendation*: CMS should define an opioid naïve patient as those patients with an opioid prescription who have not received opioid treatment over the last 30 days (or longer). CMS should permit Part D Plan P&T committees with the flexibility to develop policy that identifies exceptions or expansions to this definition.**

iii. Opioid Duplicative Therapy Safety Edits

CMS Proposal: CMS states that it expects all Part D plan sponsors to implement a soft POS edit for duplicative long acting (LA) opioid therapy beginning in 2019, with or without a multiple prescriber criterion. When such an edit is triggered for concurrent use of opioids and buprenorphine, the soft edit should only reject the opioid prescription following the buprenorphine claim and should not impede access to buprenorphine for MAT.

Discussion: As CMS cited, the use of LA opioids and a greater number of opioid prescriptions are associated with a higher risk of mortality. The use of duplicative LA opioids safety edits may proactively address potentially unsafe cumulative opioid regimens at the time of dispensing to promote care coordination before beneficiaries are identified by the OMS. We note that Part D plan sponsors will need to make systems updates in order to accommodate this change and thus we would request that CMS make this policy mandatory for 2020 but give plan sponsors the option of implementing the change in 2019.

***PCMA Recommendation*: PCMA supports a soft POS edit for duplicative LA opioid therapy; CMS should provide adequate time for needed system changes and testing.**

iv. Concurrent Use of Opioids and Benzodiazepines

CMS Proposal: CMS proposes that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit.

Discussion: PCMA supports allowing sponsors to implement the current policy for non-opioid medications, such as benzodiazepines, which permits Part D plan sponsors to address concurrent use of these drugs during case management and apply beneficiary-specific claims edits. The CDC Guidelines state that concurrent use of opioids and benzodiazepines may increase the risk

of overdose and death.[18] Given the heightened risk associated with this dangerous drug combination, Part D plan sponsors need the latitude to implement beneficiary specific claim edits for benzodiazepines and other drugs, as appropriate, to protect at-risk beneficiaries. To that end, we also recommend including sedative hypnotics with GAPAnergic (benzo-like) mechanism of action such as zolpidem, zaleplon and eszopiclone. Again, we request that CMS give plans the option of implementing this change for 2019 (and mandatory for 2020) while Part D plan sponsors make the necessary systems updates order to accommodate this policy.

PCMA Recommendation: PCMA supports the CMS proposal for Part D sponsors to implement a concurrent opioid and benzodiazepine soft POS safety edit. CMS should also include sedative hypnotics with GAPAnergic mechanism of action such as zolpidem, zaleplon and eszopiclone. CMS should mandate this change for 2020, while giving plan sponsors the option of implementing it for 2019.

c. Access to MAT

CMS Proposal: Consistent with FDA's position, CMS states that it will not approve prior authorization (PA) criteria for medication-assisted treatment that requires a beneficiary to obtain an authorization any more frequently than once during a plan year. Further, when a sponsor has authorized MAT for a beneficiary in the prior plan year, CMS expects that the sponsor would carry that authorization through to the next plan year.

Discussion: PCMA agrees that it is imperative to ensure that Medicare beneficiaries have appropriate access to MAT. However, it is equally imperative for plans to have the ability to apply utilization management to MAT to help ensure safe and effective therapy. For example, many plan sponsors use prior authorization to ensure MAT is delivered in tandem with psychosocial interventions, such as cognitive behavioral therapy, which is evidence based and increases the MAT effectiveness and improves health outcomes.[19]

PCMA Recommendation: CMS should allow plan sponsors to place PA criteria on MAT as needed to help improve its effectiveness.

[18] CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, Deborah Dowell, MD, Tamara M.Haegerich, PhD, Roger Chou, MD, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC, Atlanta, Georgia, published in Morbidity and Mortality Weekly Report, Vol. 65 (March 18, 2016).
[19] The Pew Charitable Trust. Medication-Assisted Treatment Improves Outcomes for Patients With Opioid Use Disorder. November 2016. Found at: http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/11/medication-assisted-treatment-improves-outcomes-for-patients-with-opioid-use-disorder

16. Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants

CMS Proposal: Part D sponsors are responsible for determining whether immunosuppressants are coverable under Part D because immunosuppressants that are used for Medicare covered transplants are covered under Part B. As a result of CMS Program Integrity audits, CMS has learned that information obtained directly from prescribers often times is not reliable or conflicts with CMS information that is provided at a later date. In order to streamline the coverage determination process and establish CMS as the single source for transplant information, CMS is proposing new guidance on how Part D sponsors should determine whether a drug is a Part B drug and when to revise its findings if the information from CMS changes. CMS states that this proposal establishes its expectations around how Part D plans perform due diligence to ensure that this does not occur. The guidance covers three scenarios:

1. No Prior Part D Claims History for Immunosuppressants

    a. Where the plan has received information from CMS (e.g. via MARx) indicating that Medicare covered the enrollee's transplant, plans are expected to rely on the CMS information and cannot cover immunosuppressants under Part D even if information is also provided by the prescriber that indicates that the transplant was not covered by Medicare.
    b. Where the plan has NOT received information from CMS indicating that Medicare covered the transplant for the enrollee, and has not previously received information from a prescriber that the transplant was covered by Medicare, CMS expects plans to default to covering the immunosuppressants under Part D and no longer expects plans to reach out to prescribers to inquire about Medicare coverage of the transplant. Such outreach is burdensome for plans and prescribers, and has been shown to be unreliable for accurately determining if Medicare covered a transplant. Nevertheless, the plan should approach this coverage decision using the best available information; if the plan has previously reached out to the prescriber and received information indicating that the transplant was covered by Medicare (in full or in part), the Part D plan may not cover immunosuprressants under D.

2. Prior Part D Claims History AND MARx currently indicates that Medicare covered the transplant:

    A plan might have covered the drugs under Part D previously because either:

a. MARx information was updated after the Part D sponsor relied on prior information from the prescriber that the transplant was NOT covered/ paid by Medicare; or
b. The Part D sponsor had relied solely on information from the prescriber that the transplant was NOT covered/paid by Medicare without regard to MARx.

Under either scenario, the Part D sponsor must now rely on the MARx information going forward and notify the enrollee that the plan can no longer cover the immunosuppressant(s) because it is covered under Part B. No changes need to be made to prior Part D claims.

3. Prior Part D Claims History, no MARx indicator or claims history of a covered transplant BUT the Part D sponsor receives information from CMS (e.g. as part of a CMS Program Integrity audit or otherwise) that the transplant was covered by Medicare.

   Under this scenario, the Part D sponsor must now rely on the CMS information going forward and provide notice to the enrollee that the plan will no longer cover the immunosuppressant(s) under Part D because it is covered under Part B. No changes need to be made to prior Part D claims.

Discussion: PCMA and its members really appreciate the efforts of CMS to provide written guidance on this important topic. While we generally agree with the approach outlined with respect to kidney transplants, it reinforces that this same scope of issues needs to be addressed by CMS regarding the wide range of transplants other than kidney. In fact, we understand that the kidney transplant information captured in the MARX system represents only about half of the Medicare covered transplants. It is not clear to us what are the barriers for CMS to be able to provide eligibility files to Part D plan sponsors for these other types of transplants. Indeed, such a system would obviate the need for Part D plan sponsors to even have to reach out to prescribers for information on the beneficiary's transplant.[20] A related issue is the time lag as to when data appears in MARX. Any steps the Agency could undertake to improve that lag would be very helpful in this arena.

PCMA Recommendation: PCMA supports the clarification of CMS policy regarding the use of best available information with respect to immunosuppressants and Part B vs. D coverage. However, PCMA is concerned that this information is available only with respect to kidney

[20] On a related note, we wanted to point out that the Budget bill recently enacted by Congress would provide Part D plan sponsors with access to Part A and B claims data as of 2020. However, since that data specifically would preclude Part D plan sponsors from using such data for coverage determinations, it is not clear how Part D plan sponsors could use such data to make the Part B versus Part D coverage determination as envisioned in the Draft Call Letter.

transplants and thus urges CMS to make available to Part D plans comparable information in as close as possible to real time for all other types of transplants.

17. <u>Using the Best Available Information when making B vs D Coverage Determinations for Inhalation Durable Medical Equipment (DME) Supply Drugs</u>

<u>CMS Proposal</u>: CMS is seeking to clarify how Part D plans can determine that a beneficiary is residing in a LTC facility. Medicare Part B covers certain inhalation drugs as supplies under the DME benefit, which is not available to beneficiaries residing in LTC facilities. If the beneficiary is not in a Part A stay in one of these facilities, these inhalation drugs can be covered under Part D. Therefore, CMS permits Part D sponsors to rely on a patient residence code of "3" or "9" on a pharmacy claim for determining when such inhalation drugs may be covered under Part D. CMS also expects that sponsors will pay claims for these products only when the pharmacy claim includes these specified patient residence codes regardless of any prior coverage determination based upon a prescriber statement indicating that the beneficiary resides in a LTC facility (i.e. the prescriber statement and patient residence code must be aligned).

<u>Discussion</u>: As with the use of best available information for immunosuppressants discussed above, PCMA and its members truly appreciate the efforts of CMS to provide written policy guidance on this topic. We agree with the approach set forth and believe it provides a reasonable standard to differentiate between Part B and Part D LTC coverage for immunosuppressants. However, there remains a significant open question where similar CMS guidance needs to be provided. Specifically, the open issue relates to how Part D plans can verify whether the beneficiary's stay in the LTC facility is still in the Part A phase of the Medicare benefit.

Currently, plans have to get Part A information from the LTI Report, which is typically very out-of-date. If this piece of the puzzle could be addressed, Part D plans and their PBMs would have a complete process for determining appropriate Medicare coverage.

<u>PCMA Recommendation</u>: PCMA supports the clarification on CMS policy regarding the use of best available information with respect to inhalation DME supply drugs and Part B vs. D coverage. CMS should provide a policy or mechanism for plans to verify if the beneficiary is in the Part A phase of LTC coverage.

18. Part D Mail-Order Refill Consent Policy– Solicitation for Comments

CMS Proposal: In the 2014 Call Letter, CMS stated that Part D sponsors should require their network retail and mail-order pharmacies to obtain patient consent to deliver a new or refill prescription prior to each delivery in an attempt to decrease the waste and unnecessary costs associated with unneeded or unwanted prescriptions. CMS subsequently exempted EGWPs from the mail-order patient consent restrictions and also allowed automatic shipment of new prescriptions received directly from the prescriber.

CMS has received requests to further modify or eliminate this policy. Some stakeholders suggest that the current policy creates an unnecessary burden and interferes with improving medication adherence via automatic refill shipments. However, CMS remains concerned that auto shipments of refills not specifically requested by beneficiaries increase shipments of unnecessary or unwanted prescription refills, leading to increased waste and potentially inappropriate drug therapy when a discontinued medication is shipped.

CMS is interested in (1) any information and data associated with mail-order auto-ship programs (other than those dealing with on-time refills, medication possession ratio, or proportion of days covered) that indicate actual improved adherence by patients resulting from automatic (not patient-initiated) refills, and (2) any information or data that rebuts concerns that such programs increase waste (to include unwanted or unneeded medications that go unused, as well as additional cost to the beneficiary or Part D program).

CMS is also interested in receiving feedback on possible modifications to the current policy if it determines that a change is warranted. For example:

- Replacing affirmative prior consent for refills with a refill shipping reminder, prior to shipping, which provides sufficient time for a beneficiary to cancel an order;
- Eliminating affirmative prior consent for refills but expecting plans to implement a full refund policy for any refills auto shipped that a beneficiary reports or returns as unneeded or otherwise unwanted. CMS welcomes feedback on possible approaches to confirm medications reported as unwanted were partially or fully unused; and
- Modifying the current condition of annual beneficiary confirmation to continue automatic deliveries to be more frequent, such as bi-annual; or to continue automatic deliveries but with an opt-in on a per drug basis.

Discussion: PCMA commends CMS on its willingness to revisit its Part D Mail-Order Refill Consent Policy and the request for stakeholder feedback on potential modifications. In the 2014 CMS Call Letter, CMS announced that starting January 1, 2014, Part D sponsors should require

their network pharmacies offering automatic shipments or home delivery of prescriptions to obtain beneficiary or authorized representative consent prior to delivery of prescriptions. Since this announcement, PCMA and its PBM members have voiced concern that the CMS policy places unnecessary hurdles to the use of home delivery in Part D. Even though Part D plans and their PBMs have now invested significant resources and expenses in coming into compliance with requirements, PCMA urges CMS to adopt a consent policy that permits a one-time initial authorization for automatic mail-order prescription delivery services. We believe such a policy will help facilitate greater consumer choice, improve health outcomes, and reduce costs for Part D enrollees.

Providing beneficiaries the choice to opt into an autofill delivery service, coupled with the right patient education and safeguards in place, will enhance patient adherence and lower costs, while eliminating the current challenges patients face with validating each refill delivery. For example, a recent study about the mail-order pharmacy experience of U.S. veterans living with AIDS and HIV found that while the overall experience with mail-order pharmacy services was positive, veterans faced medication access issues due to running out of prescription supply caused in part by refill ordering procedures and processes.[21] In disease areas where medication adherence is vital for the treatment and management of the condition, empowering the patient with the option of enrolling in an automatic mail order refill program to ensure access is sound policy.

Mail-order pharmacy programs reduce premiums and improve clinical outcomes by allowing extended-day supplies, which result in better adherence rates[22] and utilizes a more cost-efficient distribution channel.[23] Moreover, studies show that synchronized refill programs for mail-order

[21] Desai KR, et. al, "**Mail-order pharmacy** experience of veterans living with AIDS/HI," Res. Social Adm. Pharm., 2018 Feb; Vol. 14 (2), pp. 153-161.

[22] Tran, J, et al., "Adherence to Chronic Therapeutic Classes of Medications in Mail Service Users," Journal of Managed Care & Specialty Pharmacy, Supplement, Volume 20, Number 4-a. April 2014. Accessed at: http://www.jmcp.org/pb-assets/Poster%20Abstract%20Supplements/April2014Supp4a.pdf (finding higher medication adherence across multiple therapeutic classes of chronic medications for patients who used mail order pharmacies); Zhang, L, et al., "Mail-order pharmacy use and medication adherence among Medicare Part D beneficiaries with diabetes," Journal of Medical Economics. 14(5): 562-567 (2011); Am. J. Man. Care 19(11): 882-887 (2013),"Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes," Accessed at: http://www.ajmc.com/journals/issue/2013/2013-1-vol19-n11/safety-and-effectiveness-of-mail-orderpharmacy-use-in-diabetes; Schmittdiel, J, et al. "The Comparative Effectiveness of Mail-Order Pharmacy Use vs. Local Pharmacy Use on LDL-C Control in New Statin Users," J. Gen. Intern. Med. 26(12): 1396-1402 (2013).

[23] U.S. Department of Defense, Inspector General, "The TRICARE Mail Order Pharmacy Program Was Cost Efficient and Adequate Dispensing Controls Were in Place," p. 3, July 24, 2013. Assessed at http://www.dodig.mil/pubs/documents/DODIG-2013-108.pdf (showing that prescription mail-service programs cost 16.7 percent less than prescriptions obtained from retail pharmacies).
; Congressional Budget Office, "Prescription Drug Pricing in the Private Sector," p. 3, January 2007. Assessed at https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf (estimating average pharmacy prices and determining that retail pharmacies pay more for single-source brand-name drugs than mail-service pharmacies, because mail-service pharmacies can negotiate better rebates due to higher volume and ability to influence market shares); Pharmaceutical Care Management Association, "New Research: Mail-Service and Specialty Pharmacies to Save Consumers, Employers, Unions and Public Programs $311 Billion," September 2014. Assessed at http://www.pcmanet.org/research/new-research-mail-service-and-specialty-pharmacies-to-save-consumersemployers-unions-and-public-programs-311-billion (finding that mail-service pharmacies could save an estimated $5.1 billion for consumers, employers, and other payers in 2015, and $59.6 billion over the 10-year period 2015-24).

pharmacies could enhance adherence for common maintenance medications.

a. For example, a study conducted on medication adherence in Medicare Advantage patients receiving **mail-order** refills for common maintenance medications (antihypertensive, lipid-lowering, or antidiabetic agents) found that synchronizing refills might be a promising intervention for those patient with an otherwise low baseline adherence level.[24]
b. A similar study found that for those patients that traditionally fill their maintenance medications exclusively at retail pharmacies, a change to "synchronized medication refill schedules were associated with better medication **adherence[.]"**[25]
c. We are also aware of studies by some of our individual PBM members which show the improved impact on adherence resulting from automatic mail order, without contributing to drug waste or oversupply.[26]
d. While we encourage further studies as may be necessary to validate a more concrete link between patient adherence and mail-order pharmacy services as discussed in CMS' call letter, we believe enough data exists to support revisions to CMS existing policy towards a more patient-centric approach. PCMA strongly recommends that if, and when, a beneficiary believes that enrolling in an automatic refill mail order pharmacy program would help to improve their access to necessary prescriptions and their medication adherence, such a program should be permitted.

In response to CMS's interest in receiving feedback on possible modifications to the current policy if it determines that a change is warranted, an automatic prescription refill program should be designed as an opt-in beneficiary enrollment without the requirement to obtain prior patient consent to deliver a refill prescription prior to each mail-order pharmacy delivery. Mail-order pharmacies should be allowed to utilize an electronic (text, email, smart app technology) or telephonic refill reminder notification system to allow beneficiaries enrolled in the program to notify the mail-order pharmacy that an individual prescription refill is not needed or wanted. This process should provide sufficient times for an enrollee to cancel an order and prevent any waste. The assumption should be that if a beneficiary does not cancel an order, he must therefore desire the refill. A mail-order pharmacy should have a return policy that provides a specific safeguard allowing beneficiaries to return medications to the pharmacy in the event that a new prescription initiated by a prescriber is unneeded or unwanted. The refund policy should also be structured to encourage enrollee disenrollment from the automatic refill program as an option to prevent future instances of the receipt of unwanted automatic refills.

[24] Doshi, Jalpa A., et. al., "A Synchronized Prescription Refill Program Improved Medication **Adherence,"** Health Affairs. Aug2016, Vol. 35 Issue 8, p1504-1512. 9p.
[25] Doshi, Jalpa A., et. al "Synchronized Prescription Refills and Medication Adherence: A Retrospective Claims Analysis," American Journal of Managed Care. Feb2017, Vol. 23 Issue 2, p98-21. 28p.
[26] This data is being submitted directly to CMS in individual company comments.

We do not agree with the suggestion to modify the current condition of annual beneficiary confirmation to continue automatic deliveries to be more frequent, such as bi-annual. We are not sure what this would achieve, since enrollees are already able to stop a refill at any time.

***PCMA Recommendation*: CMS should remove the current barriers to the use of home delivery in Part D, such as mandatory beneficiary authorization for each specific prescription. Instead, CMS should allow plans to offer enrollees the option of enrolling in an automatic mail-service refill program that permits a one-time initial authorization, with appropriate safeguards (as noted above).**

CALL LETTER PROCESS ISSUES FOR CMS CONSIDERATION

PCMA would like to reiterate for CMS the importance of this Draft Call Letter comment process – and the notice-and-comment process in general – in ensuring public notice and input prior to the issuance of any new rule or policy which binds regulated entities. In particular, we reiterate for CMS (1) the necessity of this Advance Notice and Draft Call Letter comment period for finalizing any policy changes for the 2019 plan year; (2) the general requirement that any substantial rulemaking be done through formal notice-and-comment rulemaking as part of the NPRM process; and (3) the general impermissibility of finalizing any substantive policies through Interim Final Rulemaking.

In particular, and in light of the anticipated release of the Final CY 2019 Part C and Part D Policy and Technical rule, PCMA is concerned that CMS may attempt to include within the final Call Letter policies that the agency intends to finalize or finalizes in the Final CY 2019 Part C and Part D Policy and Technical rule. It is clear, under agency practice, Administrative Procedure Act rules, as well as recent guidance from the US Department of Justice (DOJ), that such a decision would be wholly impermissible. In addition, we are equally concerned about including *any* policies in the Call Letter process that are more appropriately included in the NPRM process.

We particularly would like to call attention for the agency the recent enforcement memorandum issued by the DOJ entitled "Limiting Use of Agency Guidance Documents in Affirmative Enforcement Cases"[27] which reiterates, reinforces, and builds upon the DOJ's long-held prohibition on issuing guidance documents that effectively bind the public without undertaking a notice-and-comment rulemaking process. If CMS does intend to finalize any policies in the FY 2019 Policy and Technical rule which could have a subsequent impact on policies included in the

[27] On January 25, 2018, then –U.S. Associate Rachel Brand issued a memorandum entitled, "Limiting Use of Agency Guidance Documents in Affirmative Enforcement Cases," (available at https://www.justice.gov/file/1028756/download).

Call Letter, CMS is obligated to delay these policies until the public has had sufficient time to review and comment on such policies (e.g., in the CY 2020 Advance Notice and Draft Call Letter.) Moreover, the agency is wholly prohibited from including in the Call Letter process any policies which "bind the public" and are subject to formal NPRM procedures.

PCMA Recommendation*: In light of the likely close timing between the anticipated publications of CMS's Final 2019 Policy and Technical Rule and the Final 2019 Call Letter, PCMA urges CMS to refrain from finalizing any policies in the upcoming Call Letter that were not available for comment as part of this Advance Notice and Draft Call Letter. In particular, CMS should refrain from finalizing any policies in the Final Call Letter that were not subject to comment in this Advance Notice and Draft Call Letter, *even if* such policies are finalized in the upcoming final Part D Policy and Technical Rule. CMS should also refrain from finalizing any substantive policies that are not subjected to full NPRM procedures. Such actions would run afoul of agency past practice, as well as recent guidance from the DOJ's enforcement memorandum.

OTHER TOPICS IN NEED OF CMS GUIDANCE

Finally, with the enactment of the BBA subsequent to the release of the Draft Call Letter, which contains several provisions effective for the 2019 calendar year, it would be appreciated if CMS would provide guidance needed for implementation on a timely basis. We recognize that this guidance might be provided through OACT or otherwise and not through the final Call Letter but we wanted to call out two provisions of particular importance for the Part D bids:

- **Part D coverage gap and manufacturer discount:** Closes the Part D coverage gap in 2019 instead of 2020 by accelerating a reduction in beneficiary coinsurance from 30 percent to 25 percent in 2019; also increases the discount provided by manufacturers of brand-name drugs in the coverage gap from 50 percent to 70 percent, beginning in 2019. Starting in 2019, Part D plans will cover the remaining 5 percent of costs in the coverage gap, which is a reduction from the current level of 25 percent). The manufacturer discount will continue to count towards a beneficiary's TrOOP.
- **Biosimilars:** Beginning in 2019, biosimilars will be treated the same as other brand-name drugs in the Part D coverage gap, with manufacturer discounts of 70 percent.