UNITEDHEALTH GROUP

March 5, 2018

Seema Verma, Administrator
The Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2017-0163
P.O. Box 8016
Baltimore, MD 21244-8013

Submitted electronically via http://www.regulations.gov

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 (Advance Notice/Draft Call Letter)

Administrator Verma,

UnitedHealth Group (UHG) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) comments on the Advance Notice and Draft Call Letter; 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.

UHG appreciates CMS' steps to put the MA program on a stable path for 2019, and the proposed +1.84% rate environment will ensure the 20 million beneficiaries whom elected MA continue to have access to the high quality care offered by the program. UHG urges CMS to implement the proposed +1.84% rate environment and believes that any material changes between the Proposed and Final 2019 MA and Part D Rate Notice Rules could compromise the MA and Part D programs' ability to improve health outcomes, reduce health care costs, and provide coordinated, value-based care to beneficiaries.

UHG is dedicated to helping people live healthier lives and making our nation's health care system work better for everyone through two distinct business platforms – UnitedHealthcare, our health benefits business, and Optum, our health services business. Our workforce of 260,000 people serves the health care needs of more than 139 million people worldwide, funding and arranging health care on behalf of individuals, employers, and the government. As America's most diversified health and well-being company, we not only serve many of the country's most respected employers, but we are also the nation's largest Medicare health plan – serving nearly one in five seniors nationwide – and one of the largest Medicaid health plans, supporting underserved communities in 28 States and the District of Columbia.

UHG is committed to a payment system based on quality and value instead of volume. UnitedHealthcare has nearly $65 billion in value-based payment models today, and is on track to have $75 billion in value-based payment models by 2020. As part of this commitment, UnitedHealthcare has more than 1,000 Accountable Care Organizations within its network of care

providers, with more than 16 million beneficiaries accessing care, from physicians in clinical quality programs focused on population-based management and value-based arrangements and over 110,000 physicians and 1,100 hospitals participating in value-based care programs. Optum is tackling the biggest challenges in health care by partnering across the health care system. For example, Optum provides care directly to more than 14 million people through more than 30,000 physicians, 1,100 primary, urgent and surgical care centers, and more than 1.2 million in-home primary care health visits per year.

As you know, MA is delivering superior results to 20 million beneficiaries today, including 37% who have fixed annual incomes at or below $20,000. MA's high-quality, coordinated care approach results in beneficiaries experiencing 20% fewer hospital readmissions and a 20% increase in annual preventive care visits as compared to beneficiaries in Fee-for Service. In fact, MA is providing proven innovation in an effective and consumer-friendly manner with 91% of beneficiaries reporting they are satisfied with MA. UHG is committed to high-quality, affordable care for MA beneficiaries and enrolls more than 85% of its enrollees in MA plans with four stars and above, and deploys best practices in health care, such as our HouseCalls program that has resulted in up to a 14% reduction in hospital readmissions.

UHG specifically applauds CMS' policy proposals in the 2019 MA and Part D Advance Notice to:

- Bring predictability and stability to the CMS Star Rating System by announcing changes during the annual Rate Setting process;
- Enable Value-based Insurance Design by expanding its interpretation of the uniformity of benefits to reduce cost sharing for certain benefits and offer specific tailored supplemental benefits for MA beneficiaries;
- Move forward with a demonstration model that allows MA to qualify as an Advanced Alternative Payment Model (APM);
- Drive value for Employer Group Waiver Plans (EGWP);
- Increase flexibility to the MA and Part D programs to address opioid overuse and drive towards the implementation of Centers for Disease Control and Prevention (CDC) Guidelines; and
- Consider allowing Part D plans more flexibility to complete auto-ship prescription refills, which will increase beneficiary medication adherence and decrease costs.

For 2019, CMS' proposed overall rate environment will ensure that the MA program delivers the high-quality, effective, and innovative health care that seniors deserve. We oppose substantial changes to the proposed 2019 MA and Part D Advance Rate Notice, such as changes to the coding intensity adjustment. Such changes will compromise the stability and value that the MA and Part D programs bring to beneficiaries, taxpayers, and the health care system. UHG values long-term payment stability and looks forward to partnering with CMS as it works to achieve the highest quality health care system for seniors.

As always, UHG welcomes the opportunity for constructive discussion and collaboration as part of this comment process, and we look forward to sharing any additional data or information that supports beneficiaries, CMS, and American taxpayers. We are committed to providing Medicare beneficiaries with stable access to care and affordable coverage, and ensuring that our plans continue to facilitate good consumer decision-making, improve outcomes and quality, and provide excellent value to beneficiaries.

Sincerely,

Brian Thompson, CEO
UnitedHealthcare Medicare & Retirement

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Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model

In the 21st Century Cures Act (Act), Congress directed that CMS's risk adjustment model take into account the total number of diseases or conditions of an individual enrolled in an MA Plan and make additional adjustments as the number of diseases or conditions of an individual increases. CMS now proposes to implement a new Payment Condition Count risk adjustment model that includes additional Health Hierarchical Condition Categories (HCCs) and updated data. CMS intends to phase in the new model beginning with payment year 2019. Specifically, CMS proposes that the risk adjustment model in 2019 calculate risk scores by adding 25 percent of the risk scores based on the new Payment Condition Count model with 75 percent of the risk scores from the 2017 risk adjustment model. These percentages would be phased in at 50%/50% in 2020 and 75%/25% in 2021. In 2022, the risk score would be calculated entirely (100%) under the new model.

In addition, CMS is proposing a change to the application of each risk adjustment model based on the method of data submission. Currently MA Plans submit data through two different processes, the Risk Adjustment Processing System (RAPS) and the Encounter Data System (EDS). For 2019, CMS is proposing the 2017 risk adjustment model would be applied to data submitted through RAPS and the new Payment Condition Count model would be applied to the combination of data submitted through EDS and inpatient data from RAPS.

CMS also provided risk adjustment coefficients for alternative risk adjustment models. One alternative includes all conditions (All Conditions Count Model) and a second alternative, that excludes count variables (No Count Model). Both alternatives added HCCs for mental health, substance use disorder, chronic kidney disease (CKD) and used updated data.

UHG appreciates and agrees with CMS's emphasis on expanding HCCs to include mental health and substance abuse. However, UHG does not support the proposed Payment Condition Count Model, nor would it support an All Condition Count Model. Neither model provides any greater predictive value over the current risk adjustment model and would add a significant amount of administrative burden to both CMS and MA Plans. The combination of the new phase-in approach based on data submission source with the introduction of more model variables (condition counts) increases the overall complexity of calculating an accurate risk score and understanding year-over-year changes/trends to inform bid and financial submissions.

UHG would support the No Count model CMS provided for comparison. We believe that the No Count model complies with the Act's requirement to take into account the total number of diseases or conditions of a beneficiary and make additional adjustments as the number of diseases or conditions increases.

Recommendation:
UHG recommends that any changes CMS makes apply to both RAPS and EDS. Multiple risk models with multiple data source submissions (RAPS and EDS) add complexity and burden to the program. UHG believes a single risk adjustment model applied to both data sources is more efficient to administer and does not sacrifice predictive accuracy.

UHG also recommends that CMS proceed with the No Count model. If CMS does not elect to implement the No Count model, of the two remaining models, UHG would prefer the Payment Condition Count Model. The Payment Condition Count model would be less administratively burdensome for MA Plans and CMS to implement than the All Condition Count Model.

UHG also believes it makes sense for CMS to add RAPS inpatient diagnoses to EDS for the CY2019 risk adjustment model, which brings more alignment between the two data sources.

Attachment I. Preliminary Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2019

Section A: MA Growth Percentage (p. 6)

Each year in the Advance Notice, CMS publishes a Growth Rate that has a substantial impact on Medicare Advantage (MA) benchmarks. In recent years, CMS began publishing an Early Preview of the growth rate prior to the Advance Notice followed by the final publication in the Final Rate Notice. In some years we have seen significant changes in the growth rate estimates over that time period. Because CMS does not provide detailed information regarding the data or process used to determine the growth rate in each publication, it is difficult for MA Plans and Part D Sponsors to provide any meaningful comment other than to react to the overall level of the growth rate itself. While we do not object to the proposed Growth Rate published in the Advance Notice, we would be concerned with any material reduction in the Growth Rate in the Final Rate Notice as we would not have an opportunity to understand the change and provide comment. UHG continues its request that CMS make the process more transparent so that interested parties can better understand how CMS arrives at these estimates and provide more meaningful comment on them.

Attachment II Changes in the Part C Payment Methodology for CY 2019

Section A: MA Benchmark, Quality Bonus Payments and Rebate (p. 9)

Cap on Benchmarks (p. 13)

Section 1853(n)(4) of the Social Security Act requires that CMS cap the benchmark for a county at the level of the county's applicable amount determined under Section 1853(k)(1). CMS interprets this as requiring it to include the Quality Bonus Payment percentage (QBP) increase in the benchmark before determining if the cap is applied.

UHG shares CMS's concerns that "stakeholders have raised about any rate-setting mechanism that diminishes incentives for MA plans to continuously improve the care provided to Medicare beneficiaries, and agrees that a primary goal of the Star Rating system for MA is to encourage plans to continuously improve the quality of the care provided to their enrollees."

The inclusion of the QBP in the MA benchmark cap reduces or eliminates quality bonuses for high-performing MA Plans. This policy undermines an MA Plan's ability to improve care and quality (i.e., care coordination, early disease identification, and prevention activities), may result in the higher premiums, decreased benefits, and less innovation in care for millions of seniors. Key activities and programs that

are deployed to improve health care quality, such as in-home primary care and wellness programs, could be compromised if the MA benchmark cap remains in place. The MA benchmark cap diminishes affordability for seniors and provides less attractive plan options. Thus, CMS should use its existing authority to eliminate this disruptive policy in the final 2019 MA Rate Notice.

UHG maintains that CMS has the authority to eliminate consideration of the QBP in applying the MA benchmark cap for high-performing plans in 2019, which is supported by a legal opinion prepared in February 2017 by Foley Hoag, as previously provided to CMS. The legal opinion notes, "*CMS has the authority to undertake a demonstration project that would lift the MA benchmark cap under section 1853(n)(4) of the Social Security Act in order to allow MA plans to obtain their full bonus potential under the MA Star Rating System as part of the 2018 MA rate setting process that would be announced in the Final 2018 Call Letter and Rate Notice*." CMS has broad authority through its Center for Medicare and Medicaid Innovation (Innovation Center) to test payment and service delivery models. Under Section 1115A, CMS would have the authority to waive MA statutory provisions to lift the MA benchmark cap for the purpose of testing whether the change would reduce Medicare spending, while preserving or enhancing beneficiary quality of care. Under section 402(a)(1)(A) of the Social Security Amendments of 1967, CMS has the authority to implement a demonstration project that would lift the benchmark cap to allow MA Plans to obtain their full bonus potential under the Star Rating System. Additionally, we believe that CMS has sufficient authority under its Innovation Center to launch a demonstration project, with the goal of testing whether such changes improve the health of beneficiaries, while reducing costs to the Medicare program.

Recommendation:
UHG strongly urges CMS to use its existing authority to eliminate the MA benchmark cap for high-performing plans in 2019.

Contract Consolidations and Quality Bonus Payment (p. 12)

The recently enacted Advancing Chronic Care, Extenders, and Social Services Act (ACCESS Act) directs CMS to calculate an enrollment weighted average of Star Ratings across contracts for which the Secretary, on or after January 1, 2019, approves a request to consolidate contracts. In the CY2019 Proposed Rule, CMS proposes the same change but did not specify whether the change would go into effect for 2018 consolidations or 2019 consolidations.

Recommendation:
UHG recommends that CMS follow the language of the ACCESS Act and apply the new changes to consolidations requested in 2019 to be effective for plan year 2020. Star ratings for contract consolidations requested in 2018 and effective for plan year 2019 should be calculated under the current methodology. UHG recommends that CMS confirm that this is the correct interpretation because MA Plans have already started planning for the 2019 plan year and consolidation of contracts may be part of that strategy.

Section B: Calculation of Fee for Service Cost (p. 15)

For 2019, CMS is proposing to continue refinements developed in prior years to update the claims data used to calculate the average geographic adjustments (AGAs) and to continue the repricing of historical data in the AGA calculation. The Fee for Service (FFS) cost for each county is a product of the national FFS cost and a county-level geographic index, also known as the AGA. CMS is planning to incorporate

updates and refinements to the AGA calculation methodology to reflect changes in the FFS payment rules. CMS will reprice historical claims data to reflect the most current wage and cost indices. CMS states that repricing historical claims along with rebasing rates for 2019 will ensure that the 2019 rates for each county reflect the most current FFS fee schedules and payment rules.

UHG appreciates that CMS released the 2016 FFS cost data by county with the Advance Notice, as this information is useful in estimating the impact of the rebasing. However, to better estimate the impact of rebasing, MA Plans also need the 2016 risk score information, on the same basis that was used in the 2018 FFS rate development, which was not provided. Without risk score information, we are unable to ascertain whether changes in county-level costs are due to risk characteristics, or irrespective of risk characteristics, in that county.

UHG respectfully requests that in future years CMS provide the risk score information along with the FFS cost data. The risk score would need to be on the same basis as used in the prior year's FFS rate development in order to appropriately calculate five-year averages on a consistent basis.

Section D: ESRD Rates (p. 22)

In its August 18, 2017, HPMS memo, "Sensipar® (cinacalcet) Furnished for the Treatment of ESRD Moving from Part D to ESRD PPS, Effective January 1, 2018", CMS stated that the drug Sensipar (cinacalcet) and the drug Parsabiv (etelcalcetide) were added to Part B coverage for dialysis patients effective January 1, 2018 and included in the ESRD Prospective Payment System bundled payment and therefore, no longer payable under the Part D benefit when used for the provision of renal dialysis services. CMS indicated that Part D Sponsors will have the opportunity to modify their 2018 formularies to add a Part B versus Part D prior authorization for Sensipar.

UHG respectfully seeks clarification from CMS to quantify how this significant increase in coverage under an MA Plan will be reflected in the 2019 FFS ESRD dialysis United States per capita cost (USPCC).

Section G: MA Employer Group Waiver Plans (p. 25)

UHG supports CMS's proposal to continue to waive the Bid Pricing Tool (BPT) bidding requirements for all MA employer/union-only group waiver plans (EGWPs) for 2019. CMS now proposes to fully transition in 2019 to using only individual market plan bids to calculate the bid-to-benchmark (B2B) ratios to set EGWP payments. If CMS finalizes this proposal, UHG recommends that CMS adjust the calculation to account for the difference in the proportion of beneficiaries enrolled in Health Maintenance Organization (HMO) versus Preferred Provider Organization (PPO) plan types between EGWPs and individual-market plans. Making this adjustment will mitigate the funding impact of using only individual bids, which will allow employer groups to more easily maintain existing benefits for their retirees and continue to encourage existing and new groups to insure their retirees through EGWPs.

As CMS is aware, HMO and PPO plans (individual or EGWPs) both deliver quality care and provide savings over Medicare FFS. However, CMS requires separate bids for individual HMO plans and individual PPO plans because it recognizes that there is a difference in costs based on how these two types of plans are operated. EGWPs are not any different from individual MA Plans in this regard--the same differential in operating costs is present in EGWP PPOs and EGWP HMOs. It is understood that HMO plans typically deliver care at a lower overall cost than PPO/Regional PPO plans due to narrower

networks, a higher proportion of value based contracting with provider incentives, and extensive coordinated care, while PPO plans provide broader geographic and provider access than HMOs, which results in higher costs. Most employer groups insure retirees across the country making a PPO the preferred product because it maximizes the number of individuals who may enroll in the MA EGWP. Notably, 95% of UHG's EGWP beneficiaries are enrolled in PPOs.

UHG believes that if EGWPs are paid the same as individual plans without accounting for the different product mixes in these two marketplaces, employer groups may consider switching to a lower cost HMO product, which would geographically limit the retirees who could be covered by these plans and reduce the number of providers and MA Plans available to retirees.

CMS's recognition of the differential in the cost of operating EGWP PPOs versus EGWP HMOs, as well as the pressures employer groups face to keep costs and benefits stable, is imperative to the continued enrollment growth in MA through EGWPs, as well as the continued savings over Medicare FFS. Without funding stability, there is no reason for employers and unions to maintain or add benefits, or even continue to purchase EGWPs, and other employers and unions will likely not see the benefit of converting their existing coverage to an EGWP. Therefore, as CMS implements its proposal to set payment rates based solely on individual bids, it should also adjust the calculation to account for the difference in the proportion of beneficiaries enrolled in HMO versus PPO plan types between EGWPs and individual-market plans.

In future payment years, CMS could also consider releasing the B2Bratios soon after it receives the prior year's individual bids, or even in the Early Preview, rather than waiting until the April release of the Final Rate Notice. This could allow EGWPs to begin their benefit planning process, which traditionally begins well before even the Advance Notice is released.

Section H: CMS-HCC Risk Adjustment Model for CY 2019 (p. 30)

Please refer to the Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the MA CMS-HCC Risk Adjustment Model.

Section I: ESRD Risk Adjustment Model for CY 2019 (p. 30)

UHG does not support CMS's proposal to implement an updated version of the ESRD risk adjustment model. UHG appreciates that CMS wants to update the model to account for the 21st Century Cures Act allowing all Medicare beneficiaries with ESRD to enroll in MA Plans beginning in 2021. However, CMS did not provide MA Plans with sufficient detail or time to allow for meaningful comment on the changes that CMS proposes. UHG suggests that CMS work with MA Plans and stakeholders to better understand the implication of ESRD FFS data to improve the risk adjustment model, particularly given that all Medicare beneficiaries with ESRD may enroll in MA Plans starting in 2021. The changes CMS is proposing may potentially cause significant disruption and could lead to a decrease in benefits, particularly for MA Plans that have a significant amount of ESRD membership. Any changes CMS may propose should be carefully designed and phased in to avoid abrupt and unintended consequences. UHG believes it is imperative that CMS provide the industry with an opportunity to sufficiently review and comment on any proposed methodology changes. UHG continues its request that CMS make the process more transparent so that interested parties can better understand how CMS arrives at its estimates and provide more meaningful comment on them.

Recommendation:
UHG recommends that CMS not proceed with its proposed changes to the ESRD risk adjustment model until MA Plans have sufficient time to review and analyze the changes and provide meaningful comment. Policy changes that have a significant effect on MA Plan payment should not be based on conclusions and inferences that are not fully substantiated. Furthermore, the Advance Notice lacks specifics on some of the detail that would be necessary for MA Plans to comment fully.

If CMS proceeds with the ESRD risk adjustment model changes, we recommend that CMS phase in any changes over several years to avoid any year over year disruption.

Section K: Medicare Advantage Coding Pattern Adjustment (p. 35)

UHG supports CMS's proposal to adopt a Coding Intensity Adjuster of 5.90%. CMS also indicates it is considering multiple methodologies to inform its final decision and refers to its prior analysis in the 2010 Advance Rate Notice, 2016 Advance Rate Notice, and MedPAC's March 2017 Report to Congress ("MedPAC Report"). Given the lack of information regarding alternative proposals, UHG urges CMS not to adopt any different amount.

CMS did not provide enough detail or a new methodology to allow MA Plans to provide meaningful comment on any alternative methodologies CMS may be considering. In the future, UHG suggests that CMS work with MA Plans and stakeholders to better understand the implication of FFS and MA data and to improve the risk adjustment model with the ultimate goal of ensuring actuarial equivalence. Any changes CMS may propose should be carefully designed and phased in to avoid abrupt and unintended consequences. If CMS does consider making any changes to this adjustment, UHG believes it is imperative that CMS provide the industry with an opportunity to review and comment on any proposed methodology.

Additionally, UHG believes that given the changes CMS is making in its FFS payment system, now is not the time to propose a new coding pattern intensity adjustment methodology. Several changes in FFS and MA in the last few years and additional planned changes may impact care practice and coding patterns in both programs, potentially in different ways. For example, CMS is changing the way it will pay eligible clinicians for Part B services with the Quality Payment Program, which is in its very early stages of implementation. Bundled payment and Accountable Care Organizations (ACOs) may also be changing FFS coding patterns and the relationship to MA. Similarly, FFS and MA have transitioned to the ICD-10 coding system and greater use of electronic medical records, which will likely affect coding patterns. When comparing MA and FFS coding patterns, CMS should consider the differences in timing of when FFS and MA are impacted by these changes. The use of two data source submissions (EDS and RAPS) and their gradual phase in to the MA risk adjustment model adds another level of complexity and change. CMS and MA Plans are operating in a new era, and any historical coding from just a few years ago may not reflect the impact of such noted changes and may misstate the MA coding pattern adjustment. UHG does not believe it would be appropriate to try to apply a new method for measuring any difference in coding patterns until the impact of the other changes is better understood. Given the fact that CMS had not provided any detail of a proposed change to allow MA Plans to comment, adopting a wholesale new methodology in the Final Rate Notice would be particularly inappropriate.

Notwithstanding the above, UHG offers the following thoughts regarding the other methodologies CMS referenced in the 2019 Advance Notice. The analysis in the 2010 Advance Rate Notice focused on the difference in trend in coding in FFS and MA versus the absolute difference. Focusing on the trend is

sensitive to the time period that is being analyzed, which as previously noted, may not lead to accurate results in periods of significant changes in coding practices such as what the industry has experienced in recent years. The analysis in the 2010 Advance Rate Notice also assumed an average "stayer" rate across the industry. This inherently penalizes MA Plans that are growing more than the average.

In the 2016 Advance Notice, CMS discussed a proposal of calibrating the coding adjustor to result in payments that, in the aggregate, are no greater than such payments, net of a variety of adjustors, would be in FFS. This proposal is based on the assumption that MA enrollees are at similar (or better) risk than FFS beneficiaries. CMS addresses three bases for this assumption (self-reported health status, mortality rates, and Part D drug information), yet UHG believes there are significant issues with each, which substantively undermines the proposal. Self-reported health status is not a reliable indicator of health status. Mortality rate is not an adequate proxy for health status because, as CMS's proposal suggests, this may be due to better quality of care in MA. Finally, the analysis on Part D drug information does not recognize the potential differences in prescription drug patterns and medical practice patterns between MA and FFS beneficiaries.

The March 2017 MedPAC Report included three main recommendations: 1) develop a risk adjustment model that includes two years of FFS and MA diagnostic data, 2) exclude diagnoses that are only documented on health risk assessments from both FFS and MA, and 3) apply a coding adjustment that fully and equitably accounts for the remaining differences in coding between FFS and MA. UHG cautions against using any of these recommendations.

First, a two-year model has the potential to be less predictable because the diagnosis data collection period is further from the payment period. There is more opportunity for the beneficiary's health status and treatment patterns to change over time.

Second, UHG does not believe that excluding "health risk assessment" diagnoses would improve risk adjustment methodology. MedPAC does not define health risk assessments. For this reason, it is impossible to know how such a program would be implemented. Moreover, CMS already has rules limiting the types of data that can be used for risk adjustment (e.g., face-to-face encounter with an acceptable provider type) that limit the ability of an MA Plan to use health risk assessments that would not also be used in FFS. For example, a health risk assessment performed by the beneficiary's primary care provider (PCP) in a face-to-face setting would produce diagnoses used in FFS or MA, whereas a telephonic interview with a Registered Nurse would not. CMS has addressed the use of health risk assessments in home visits and adopted best practices to ensure that the data used are appropriate. UHG believes the current approach best ensures that only appropriate data is used in risk adjustment.

Third, the MedPAC Report also recommended varying the MA coding pattern adjustments based on high, medium or low coding levels for a contract. UHG believes an industry wide adjustment factor leads to more equitable reimbursement for several reasons: 1) all MA Plans should be paying close attention to coding and documentation of medical records; to vary the factor would discourage accurate coding, 2) coding levels can vary from one year to the next for a given contract, and 3) beneficiaries move from one plan to another and retain the diagnosis codes assigned.

<u>Recommendation</u>:
UHG agrees with CMS's proposal to apply a MA coding pattern adjustment of 5.90%.

UHG maintains that now is not the time for CMS to propose a new coding pattern intensity adjustment methodology due changes in FFS and MA in recent years and planned changes that we expect to impact practice and coding patterns in both FFS and MA in potentially different ways. Additionally, CMS did not provide sufficient detail or information regarding a new methodology to allow for meaningful analysis or comment by MA Plans. UHG urges CMS to work with the industry to better understand the implications of FFS and MA data and to improve the risk adjustment model with the goal of ensuring actuarial equivalence. UHG welcomes the opportunity to work with CMS to inform its consideration of a new methodology.

Section O: Quality Payment Program (p. 43)

UHG supports CMS's Quality Payment Program (QPP) initiative to move toward a value and quality based payment system in original FFS Medicare. We also appreciate CMS's proposal to implement the Other Payer Advanced Alternative Payment Model (OPAAPM) option, which will allow eligible clinicians to become qualified participants (QPs) by considering their participation in other payment arrangements, including those with MA Plans. However, we still have concerns relating to how CMS will administer QPP payment adjustments due to our outstanding questions below, as well as the deadline for submitting MA Plan payment arrangements.

MA Plan Payment Arrangement Submissions for OPAAPMs

Our questions have taken on new urgency with CMS's decision to connect OPAAPM with the bid submission. Beginning with the 2019 plan year bid submission (June 4, 2018), MA Plans can voluntarily submit their payment arrangement information to CMS for its determination as to whether the arrangement qualifies as an OPAAPM. CMS will make available to MA Plans a QPP module in the 2019 bid submission package expected to be released in April 2018. We respectfully request that CMS permit additional time for MA Plans to decide whether to make their voluntary submissions of payment arrangements to CMS considering the QPP module will be first released in April. MA Plans need time to assess their provider contracts and engage with their providers regarding potential payment arrangement submissions. UHG believes that a September 1, as compared to a June 4, deadline would provide sufficient time for MA Plans to review and confer with their providers. Additionally, we request that CMS consider any payment arrangement submissions (i.e., contractual terms, incentive arrangements) from MA Plans, or subsequently from providers, to be protected as confidential information, as are the bid submissions today.

MA Plan Payments to Non-Contracted Providers (QPP Payment Adjustments)

42 CFR §422.214(a) states that a provider who is not contracted with an MA Plan must accept, as payment in full, the amounts that the provider could collect if the beneficiary were enrolled in original Medicare. However, CMS's QPP 2017 Final Rule with Comment Period (CMS-5517-FC) and the QPP Year 2 Final Rule with Comment Period and Interim Final Rule with Comment Period (CMS-5522-FC and IFC) did not clarify whether or how MA Plans must adjust payments to non-contracted providers based on their QPP status. CMS has not issued any other guidance answering this question.

If CMS requires MA Plans to pay QPP related payment adjustments to non-contracted providers, it could present operational challenges for both CMS and MA Plans. CMS could face administrative challenges relating to the initial implementation and ongoing operation of this new process including

communicating the information needed to MA Plans in sufficient time to enable MA Plans to operationalize these payment adjustments.

Knowing whether MA Plans will be expected to make QPP adjustments to non-contracted providers is also necessary for MA Plans to prepare their bids. Claims from non-contracted providers constitute an ever-increasing percentage of claims paid by an MA Plan. For example, PPO plans allow MA beneficiaries to receive services from non-contracted providers, and the projected medical spend for these MA Plans could vary significantly if the cost associated with claims from non-contracted providers needs to account for QPP adjustments. If CMS intends to require MA Plans to incorporate QPP payment adjustments (positive or negative) to non-contracted providers, we ask that CMS clarify how and when MA Plans will be notified. UHG recommends that CMS also consider providing notice of the payment adjustments after the performance year and outside of the claims processing system. This would allow MA Plans the option of recouping penalties (e.g., eRx). We believe this would be less abrasive to impacted providers and more efficient for CMS and MA Plans because it would mirror familiar processes.

Submitting 2019 bids with an actuarial certification in June 2018 without answers to our questions surrounding implementation of the QPP payment incentives puts MA Plans in the position of presuming what CMS's guidance will be and impacts the confidence of actuarial certifications. UHG requests that CMS issue definitive guidance on its outstanding questions concerning the administration of QPP payment incentives as soon as possible, but no later than April 2, 2018, to allow MA Plans sufficient time to prepare and certify their 2019 bids.

Recommendation:
UHG respectfully requests that CMS confirm whether MA Plans are required to apply QPP-related incentive adjustments to non-contracted providers. If CMS intends to require MA Plans to make QPP payment adjustments to non-contracted providers, then we ask that CMS clarify how and when MA Plans will be notified of a QP's QPP status, whether they qualify for payment adjustments and the amounts, so that MA Plans can develop implementation plans and can account for anticipated impact to medical spend in 2019 bid planning. We recommend that CMS's process mirror other bonus programs in that: payment adjustments are communicated in lump sum amounts by provider to MA Plans after the performance year, payment adjustments are expected to be paid outside of the claims adjudication process, and MA Plans will be provided the option to recoup penalties (negative adjustments). We would appreciate this information before our 2019 bids are due to CMS in June 2018.

UHG also asks CMS to clarify that its QPP adjustment amounts will have no impact to the Medicare allowable amount and how beneficiary cost-sharing will be affected, if at all.

UHG requests that CMS permit until September 1 for MA Plans to decide whether to make their voluntary submissions of payment arrangements to CMS for determination as to OPAAPMs considering the QPP module will be first released in April. We request that CMS consider any payment arrangement submissions (i.e., contractual terms, incentive arrangements) from MA Plans or subsequently from providers, to be protected as confidential information in the same manner that bids are today.

Finally, UHG seeks confirmation on whether the voluntary payer-initiated submission process of payment arrangements for CMS's determination as to qualifying as an OPAAPM applies to delegated entities of MA Plans, or strictly to MA Plans.

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2019 (p. 45)

Section A. Update of the RxHCC Model (p. 45)

CMS is proposing to update the RxHCC risk adjustment model for 2019. If CMS intends to recalibrate the proposed Part D coefficients to reflect the ACCESS Act, UHG requests that CMS provide Part D Sponsors with that information as soon as possible and in advance of the Final Rate Notice expected to be released by April 2. Part D Sponsors need sufficient time to analyze and model the impact of the RxHCC risk adjustment model changes in order to provide meaningful feedback to CMS.

Section E: Reduced Coinsurance for Applicable Beneficiaries in the Coverage Gap (p. 54)

UHG notes that since the Advance Notice was released, the ACCESS Act was passed, which modifies the coinsurance for applicable beneficiaries in the coverage gap. UHG respectfully requests that CMS release updated guidance in the 2019 Final Call Letter based on the provisions of the ACCESS Act and confirm:

- The coinsurance for applicable beneficiaries for non-applicable and applicable Part D drugs purchased during the coverage gap phase of the Part D benefit in 2019 will be 25%.
- A biosimilar drug is an applicable drug for purposes of the coverage gap phase of the Part D benefit.

Additionally, current CMS guidance stipulates that Part D Sponsor formularies must include all, or substantially all, drugs in the protected classes. With respect to biosimilars in a protected class, UHG recommends CMS allow Part D Sponsors the flexibility to manage the originator product(s) and their respective biosimilar(s) as reasonably identical, or similar drug entities, and only require one originator or biosimilar product on its formularies and not one of each.

Section H: Enhanced Medication Therapy Management (MTM) Model (p. 56)

UHG is pleased to be one of the six participants in the Part D Enhanced Medication Therapy Management (MTM) model pilot program and supports CMS in its continued efforts to implement and operationalize the model. As outlined in its 2015 memo, CMS is offering a performance-based incentive payment in return for a minimum reduction (2%) in Medicare costs of care and successful data and quality reporting. CMS indicates that given timing and operational considerations, it is currently determining whether it will be possible for the model's incentive payments to be considered when determining the 2019 low-income premium benchmarks.

As CMS is likely aware, its determination and the timing of the determination on whether the model's premium reductions will be considered will directly impact how Part D Sponsors prepare their 2019 bids. In order for Part D Sponsors to properly plan for their 2019 bids and estimate low income benchmarks, it is critical that CMS provide the following information as soon as it is available, but no later than May 1, 2018:

- Confirmation regarding the inclusion (or exclusion) of MTM model performance based incentive payments in the low income benchmark calculations.
- A list of the participating PBPs in the MTM model that will be receiving a performance based incentive payment in 2019.

UHG values the transparency and open communication that CMS has provided to participants to date and encourages CMS to continue to be transparent by providing the information requested above, to ensure Part D Sponsors can appropriately plan for their 2019 bid submissions.

Attachment VI. CY 2019 Draft Call Letter

Section I – Part C and D (p. 100)

Annual Calendar (p. 100)

May, 2018 - Final ANOC/EOC, LIS rider, Part D EOB, Formularies, Transition Notice, Provider Directory, Pharmacy Directory, and MMP models for CY 2019 Available for all Organizations (p. 101)

Release of Annual Notice of Change (ANOC)/ Evidence of Coverage (EOC), Low Income Subsidy (LIS) rider, Part D Explanation of Benefits (EOB), Formularies, Transition Notice, Provider Directory, Pharmacy Directory, and Medicare Medicaid Plan (MMP) models

CMS is proposing a May 2018 final release date for the following CMS model documents: ANOC/EOC, LIS rider, Part D EOB, Formularies, Transition Notice, Provider Directory, Pharmacy Directory, and MMP models. The current timeline does not take into account the technology updates MA Plans need to make to meet the increasing level of personalization and benefit detail required in the development of model documents. Additionally, UHG believes that steady increases in MA Plan and Part D Sponsor membership over the next few years will lead to dramatic increases in the number of documents that will need to be produced, which will only further increase production timelines. UHG recommends earlier release dates to accommodate these concerns, as well as better communication from CMS on release timelines and status updates if guidance or models will be late.

Recommendation:
UHG requests that CMS release the final models no later than April 2018.

Release of CMS Non-Renewal (NR)/ Service Area Reduction (SAR) Guidance and Model Letters

CMS requires MA Plans and Part D Sponsors that are non-renewing contracts, plan benefit packages, or reducing their service areas to notify their beneficiaries at least 90 days before the end of the current contract period and provide information about alternative enrollment options. CMS requires that MA

Plans and Part D Sponsors use the NR and SAR model notices provided by CMS and submit them in the HPMS. MA Plans and Part D Sponsors must also input actual mail dates and the number of impacted beneficiaries into HPMS.

Over the last several years, CMS has released the SAR model notice toward the end of September (e.g., September 21, 2016, September 20, 2017), making it challenging for MA Plans and Part D Sponsors to meet the SAR/NR beneficiary notification deadline. This late release impacts the ability of MA Plans and Part D Sponsors to create the notices, conduct internal quality assurance to confirm the accuracy of the notices, and then send the personalized beneficiary notices in time to meet SAR deadlines. It is especially challenging if CMS makes changes to any of these notices from the prior year model notice.

Recommendation:
In order to ensure that MA Plans and Part D Sponsors are able to produce and mail notices timely, we strongly recommend that CMS release the annual SAR/NR guidance and model letters with other CMS-required model documents no later than April 2018. We also request that CMS issue the SAR alternative plan information to be populated in the notices by the end of August. This will help ensure that MA Plans and Part D Sponsors have sufficient time to: (1) conduct meaningful quality assurance to ensure that accurate information is provided to beneficiaries and (2) meet the SAR/NR deadline so that beneficiaries receive their notices, Medigap rights, and alternative plan information in time to make an informed decision regarding their next year's coverage needs.

Additionally, within the CMS NR and SAR Guidance and Enrollee Notification Models, CMS notes, "Many other States have Medigap protections that go beyond federal requirements. The State-specific information can be obtained by contacting your local SHIP office or State Department of Insurance." Based on the potential challenges in trying to obtain this information to develop MA Plans' state-specific notices and to ensure that the language in the Medigap notices is consistent across MA Plans and Part D Sponsors, we believe that CMS should either:

- Provide the State-specific Medigap notices to MA Plans and Part D Sponsors for all states that have special requirements beyond the federal requirements (as CMS already does for Massachusetts, Minnesota, and Wisconsin) OR
- Include standard language in the model general Medigap document, What You Should Know About Medigap (Tab F). Under the section Get Help Comparing Your Options, there is language that currently states, "Call <Name of SHIP> at <SHIP Phone>. Counselors are available to answer your questions, discuss your needs, and give you information about your options and Medigap policies. All counseling is free. TTY users should call <SHIP TTY>." We respectfully recommend that CMS add a statement to this section that says, "Your state may have additional Medigap requirements. To find out, call your SHIP office."

Mid to Late June, 2018 - Release of the CY 2019 Medicare Marketing Guidelines (MMGs) in HPMS (p. 102)

CMS proposes to release the 2019 MMGs in mid to late June 2018. The current timeline does not take into account the technology updates MA Plans need to make to meet the changes outlined in the MMGs. Additionally, the late release (as in July 20, 2017 for CY2018) of the MMGs places an undue burden and cost on MA Plans and Part D Sponsors to implement any new changes described in the MMGs in time to have the ANOC document to beneficiaries by the September delivery deadline.

Recommendation:
MA Plans and Part D Sponsors cannot submit 2019 marketing materials until the final CMS MMGs are released. As such, UHG recommends that CMS release the final 2019 MMGs no later than April 2018 to allow MA Plans and Part D Sponsors time to make adjustments to their 2019 marketing materials prior to submitting them for CMS review when the HPMS Marketing Module opens on June 1, 2018. Additionally, UHG requests better communication from CMS on final release timelines and status updates if guidance or models will be late.

September 30, 2018 - Deadline for Plans to Provide Documents to Current Enrollees (p. 104)

In 2018, CMS removed the requirement to send beneficiaries a Multi-Language Insert (MLI). However, the 2019 Draft Call Letter appears to require MA Plans and Part D Sponsors to include the MLI in its September 30, 2018 ANOC mailing. The MLI is not needed, as it is duplicative of the current ACA 1557 requirements, which apply to MA Plans and Part D Sponsors.

Recommendation:
UHG requests CMS clarify that any reference to the MLI in the 2019 Call Letter refers to the notices and taglines required under ACA Section 1557 and that plans are not required to separately provide the MLI.

In addition, the ANOC portion of the Annual Calendar does not reflect the CY2019 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4182-P) (82 FR 56336) (CY2019 Proposed Rule) which would allow MA Plans and Part D Sponsors the flexibility to provide the EOC electronically and the EOC/Directories/Formulary separate from the ANOC and by October 15, 2018. To the extent CMS finalizes those proposals, which UHG supports, UHG asks that CMS make similar changes in the CY2019 Final Rule.

Enhancements to the 2019 Star Ratings and Future Measurement Concepts (p. 110)

UHG thanks CMS for soliciting feedback on potential changes to the 2020 Star Ratings and other measurement concepts in this Advance Notice. UHG believes that CMS makes the Star Ratings system more predictable and stable by inviting comments earlier in the process and increasing the amount of time potential new measures stay on the Display page.

Statin Use in Persons with Diabetes (SUPD) (Part D) (p. 107)

While UHG supports CMS's proposal to add the SUPD measure with a weight of 1 for plan year 2019 and a weight of 3 for subsequent years, we continue to ask that CMS consider how to account for situations when a statin may not be clinically appropriate for a beneficiary with diabetes, (e.g., a beneficiary with a life expectancy of less than a year, dementia, metastatic cancer, an inability to tolerate statins, etc.). UHG also supports CMS's proposal to expand the data sources used to identify all Part D beneficiaries with ESRD for exclusion from the measure to include ICD-10-CM codes in both Medicare Part A and B claims and RAPS RxHCCs.

Recommendation:
As Prescription Drug Events (PDEs) are currently the only data source for the measure, yet do not contain all of a beneficiary's clinical data, we ask that CMS consider accepting supplemental data or determine an alternative way to take into account beneficiaries for whom a statin may not be clinically appropriate. In addition, UHG recommends that CMS align the exclusion list with HEDIS specifications

and exclude pregnancy, in vitro fertilization, estrogen agonists medications, cirrhosis, myalgia, myositis, myopathy or rhabdomyolysis.

Statin Therapy for Patients with Cardiovascular Disease (Part C) (p. 107)

UHG recommends that CMS not add this measure to the 2019 Star Ratings, as it is duplicative of the Medication Adherence Statin measure. We are also concerned about the large number of patients who may fall into the denominator for this measure from a single outpatient diagnosis of atherosclerosis of the extremities, or unspecified atherosclerosis.

Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications (Part D) (p. 109)

UHG supports CMS's proposal to expand its data sources for identifying all Part D enrollees with ESRD for exclusion from the measures to include ICD-10-CM codes found in both Medicare Part A and B claims and RAPS RxHCCs. In combination with the existing Medicare Enrollment Database ESRD indicator, these new data sources will allow for a more holistic means of identifying members with ESRD.

Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D) (p. 109)

UHG supports CMS's proposal to concatenate consecutive stays to create a single admission and discharge date for the Proportion of Days Covered (PDC) adjustment.

MPF Price Accuracy (Part D) (p. 110)

UHG generally supports CMS's proposal to change the MPF Price Accuracy measure to better measure the reliability of a contract's MPF advertised prices. UHG specifically supports CMS's proposal to increase the claims included in the MPF Price Accuracy measure by expanding the days' supply of claims and identifying additional retail claims using the PDE-reported Pharmacy Service Type code. UHG does not, however, agree with the methodology proposed that would result in a difference of $0.01 between the cost of the claim reported on the PDE and the price listed on MPF negatively impacting a plan's Star Ratings. Penalizing Part D Sponsors for claims with price differences of $.01 does not provide beneficiaries with a true indicator of price reliability. We also reiterate previous feedback UHG has provided on some of the inherent challenges with the measure itself. In practice, prices can change daily but MPF is only refreshed every two weeks. In addition, only one price can be submitted per drug/dosage/form when there can be price variance across National Drug Codes (NDCs) within a single specific drug/dosage/form. These challenges are exacerbated when CMS penalizes Part D Sponsors for de minimis differences in pricing.

Recommendation:
UHG recommends that the cost reported on a PDE exceed the MPF price at a minimum by $.49 for 30 days and $.99 for 90 days for the difference to count in the "Total number of claims where PDE is higher than MPF" portion of the Claim Percentage index score. We also recommend CMS provide the 2017 simulation studies with the new methodology that it is proposing. Finally, we recommend CMS provide the preview files in the same format as last year and that CMS provide them after completion of quarter 1 so that Part D Sponsors receive the file by the end of April 2018. This will allow Part D Sponsors additional time for review and comment.

Disaster Implications (p. 134)

UHG supports the proposed disaster adjustment methodology and CMS's efforts to take into consideration how these unfortunate events could impact the 2019 Star Ratings program for beneficiaries in disaster areas. Given the complexity of the adjustment, we ask for the following clarifications on the methodology.

Identification of Affected Contracts

UHG would like to confirm that a beneficiary will be identified as affected if they live in an Individual Assistance County during the incident period of a Major Disaster Declaration. For this disaster adjustment, which Major Disaster Declarations are in scope? Further, we would like to confirm that the Part C Monthly Membership Report from CMS will be the source used to determine which county a beneficiary lived in and when. Further, we would like to confirm that the disaster methodology of the 25% on the measure logic and the 60% on the cutpoint logic will be applied to all contracts affected, regardless of the requested status submitted by MA Plans.

Better of Two Year Star Ratings Adjustments and Improvement Measure

UHG would like to confirm that the Better of the Two Year Star Ratings (and corresponding measure ratings) and measure scores means that, along with receiving the better of the two years' measure level Star Ratings, the measure will be excluded from the improvement measure.

Cutpoints for Non-CAHPS

Given that the Call Center and Appeals Star Ratings are excluded from the measure level adjustments, UHG asks whether contracts that have more than 60% of their membership in a disaster area during a disaster period will still be excluded from the cutpoint clustering algorithm for these measures? UHG would also like to confirm that if a contract defaults to a prior year Star Rating, but does not meet the 60% membership threshold to be excluded from the cutpoint clustering, their current year measure rate will be included in the clustering algorithm, rather than their prior year measure rate.

Plan Makes Timely Decisions about Appeals (Part C). (p. 140)

UHG requests that CMS offer clarity within the technical specifications that this Display measure will only incorporate dismissals that are the result of untimely reconsideration cases.

Hospitalizations for Potentially Preventable Complications (Part C) (p. 141); Plan All-Cause Readmissions (Part C) (p. 145); & Transitions of Care (Part C) (p. 148)

UHG appreciates CMS's and NCQA's efforts to transition to objectively measurable metrics rather than using surveys to measure care coordination. We also believe that care coordination needs to happen across the health system and our ability to intervene during admission and after a discharge is largely dependent on when MA Plans learn their members were admitted or discharged. UHG currently has programs and incentives in place to learn about admissions and discharges as they happen, but we additionally advocate that CMS continue to consider new ways to hold providers and hospitals accountable for care coordination and information sharing.

High Risk Medication (Part D) (p. 141)

UHG recommends that CMS consider retiring the High Risk Medication (HRM) measure. The drug list for the new Polypharmacy measures that CMS is evaluating is similar. As a result, if the Polypharmacy and HRM measures were all in place, a Part D Sponsor could be penalized more than once for the same clinical concern, (i.e., a beneficiary receiving prescription fills for the same drug listed in multiple measures).

While Pharmacy Quality Alliance (PQA) has updated the HRM drug list and made changes to the criteria to include beneficiaries with at least two fills of the same HRM drug on different dates of service, UHG continues to respectfully recommend that if CMS is considering HRM to be a future Star Rating measure that it offer flexibility to Part D Sponsors in the formulary design for drugs considered high risk medications in the elderly. We ask that Part D Sponsors not be bound by CMS's formulary rules and regulations for drugs that are HRMs or suggest that CMS develop a "true" HRM list based on the PQA list and that medications falling within the following categories not be added to the HRM list, as management of them would be more challenging.

- Protected class medications.
- Medications that CMS requires Part D Sponsors have on the formulary (e.g., Benztropine, guanfacine).
- Medications that have no good alternatives and providers are able to effectively address drug safety through dosing (e.g., digoxin).
- Essential class medications as determined by the Pharmacy and Therapeutics committee (e.g., methyldopa).

Antipsychotic Use in Persons with Dementia (APD) (Part D) (p. 141)

UHG believes CMS should retire the APD Display measure, which measures the percentage of beneficiaries 65 or older with dementia who received prescription fills for antipsychotics without evidence of a psychotic disorder or related condition. In a study published in Journal of the American Medical Association (JAMA) Psychiatry (JAMA Psychiatry. 2015;72(5):438-445, Antipsychotics, Other Psychotropics, and the Risk of Death in Patients With Dementia, Number Needed to Harm) the authors indicate that while antipsychotic medications are associated with increased mortality in older adults with dementia (~2-3.8%), their absolute effect on risk relative to no treatment or an alternative psychotropic is unclear. The study also indicated that the risk of mortality appears to increase with dose.

In addition, the American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults directs providers to avoid prescribing antipsychotics for behavioral problems of dementia or delirium unless nonpharmacological options (e.g., behavioral interventions) have failed, or are not possible, and the older adult is threatening substantial harm to self or others. This suggests that there are circumstances where the benefit of prescribing an antipsychotic for a person with dementia without evidence of a psychotic disorder or related condition can outweigh the risk.

The APD measure does not take into account using the lowest effective dose of the antipsychotic or instances where these medications may be clinically appropriate based on a risk-benefit assessment made by the provider that takes into account the beneficiary's current condition, prognosis, quality of life, lack of other therapeutic options, etc. Accordingly, this potential Star Rating measure could have the

unintended consequence of limiting the use of these medications, even for beneficiaries where it may be clinically appropriate.

In addition, given that antipsychotics have been designated as protected class drugs, Part D Sponsors are extremely limited in managing decreased utilization or the desired measurement goals through formulary and/or utilization management activities.

Recommendation:
UHG recommends that this not become a Star Rating measure.

Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D) (p. 142)

UHG believes this Display measure is duplicative and not necessary due to the programs that Part D Sponsors have in place to manage opioid utilization (e.g.; Opioid Retrospective Review, Beneficiary-Level Overutilization Monitoring System (OMS) Opioid Overutilization Management, Hard Formulary-Level Cumulative Opioid MED POS Safety Edits, etc.). These existing programs identify beneficiaries on high dose opioids over periods of time, along with the associated prescriber(s) and pharmacies. Part D Sponsors are already taking actions to address potential beneficiary abuse by confirming with prescribers that opioid therapies are appropriate through documentation and/or by attestation. In addition, as CMS indicated in the Draft Call Letter, Measure 3: Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP) does not align with the OMS recommendations for monitoring overutilization of opioids. OMS has more stringent criteria and has the ability to identify more beneficiaries that may be at risk for opioid overutilization.

Recommendation:
UHG requests that CMS not add this measure to the 2019 Part D Display page.

Transition Monitoring (Part D) (p. 143)

CMS is proposing to no longer display two separate contract-level measures, one for drugs within the classes for clinical concern and one for all other drugs. Instead, CMS would consolidate the results into one failure rate and Display measure, which would align with the Formulary Administration Analysis (FAA) Display measure.

Recommendation:
UHG recommends that CMS discontinue this Display measure. UHG does not support continuation of this Display measure, as we are concerned that, similar to the FAA Display measure, it is not a true indicator of a Part D Sponsor's ability to accurately adjudicate claims consistent with the transition benefit. Claim samples used by CMS in an audit are targeted samples and are inherently biased toward identifying potential issues. As such, a Display measure focused on audit results does not appropriately reflect a Part D Sponsor's performance or operational compliance.

Formulary Administration Analysis (FAA) Measure (Part D) (p. 143)

CMS added this Display measure in 2018 to evaluate whether Part D Sponsors are appropriately adjudicating drug claims consistent with Part D requirements and Part D Sponsors' approved benefits. For 2019, CMS is proposing to display the data as a percentage with two, instead of one, decimal place.

Recommendation:
UHG recommends that CMS discontinue this Display measure. UHG does not support continuation of this Display measure, as we are concerned that it is not a true indicator of a Part D Sponsor's ability to accurately adjudicate claims consistent with CMS-approved benefits. Claim samples used by CMS in an audit are targeted samples and are inherently biased toward identifying potential issues. As such, a Display measure focused on audit results does not appropriately reflect a Part D Sponsor's performance or operational compliance.

Controlling High Blood Pressure (Part C) (p. 145)

UHG supports NCQA's evaluation of this measure for updates based on the latest guideline changes, which include changes in overall blood pressure levels and the addition of follow-up interventions documented where appropriate. UHG supports the modifications NCQA has proposed for data collection that would reduce provider burden by allowing for electronic submission, instead of the existing chart retrieval.

Initiation and Engagement in Alcohol or Drug Dependence (AOD) Treatment (Part C) (p. 146); Depression Screening and Follow-Up for Adolescents and Adults (Part C); Unhealthy Alcohol Use Screening and Follow-Up (Part C) and; Anxiety (Part C) (p. 150-151)

While UHG recognizes the importance of clinical outcomes in these areas, MA Plans have significant challenges and limited ability to influence beneficiary and provider activity related to these measures. As such, UHG recommends that CMS not adopt these as Star Rating measures.

Telehealth and Remote Access Technologies (Part C) (p. 146)

CMS requested feedback to share with NCQA regarding the feasibility of and strategies for addressing telehealth services, especially regarding the following measures that are reported by Medicare contracts: Use of Spirometry Testing in the Assessment and Diagnosis of COPD, Adults' Access to Preventive/Ambulatory Health Services, Controlling High Blood Pressure and Comprehensive Diabetes Care.

UHG encourages NCQA and CMS to include telehealth and/or remote access technology encounters, as allowed under the current statutory definition of Medicare covered telehealth services and/or as provided by MA Plans as an MA supplemental benefit or care management program to support Medicare Part C quality measures. This would allow physicians to use newer technologies as another method to: remove patient access barriers; allow more timely care; increase care coordination; open up limited in-person access for patients with more critical face to face care needs; and still maintain high standards.

HEDIS measures requiring a visit for the denominator, numerator, or exclusion should allow telehealth and/or remote access technology encounters to be counted as eligible encounters for the relevant portion of the measure, where appropriate.

Medication Adherence (ADH) for Cholesterol (Statins) (Part D) (p. 146)

UHG supports CMS's proposal to exclude beneficiaries with ESRD from the Medication Adherence (ADH) for Cholesterol (Statins) (Part D) measure and apply this exclusion to the 2020 Star Ratings (based on 2018 data).

Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D) (p. 147)

UHG supports CMS's proposal to exclude beneficiaries eligible for CMR with fewer than 61 days of continuous enrollment in the MTM program from the denominator of this measure if they did not receive a CMR within this timeframe, but include them in the denominator and the numerator if they did receive a CMR within this timeframe. In the past, these beneficiaries have been removed from the denominator whether or not they had completed a CMR within the timeframe of fewer than 61 days of continuous enrollment in the MTM program. We appreciate CMS's proposal to include beneficiaries who completed a CMR, yet were continuously enrolled in the MTM program for fewer than 61 days, in the measure. Including these beneficiaries allows for the overall results of the program to align with the work effort and also includes beneficiaries who have participated in the MTM program and had the opportunity to benefit from the completed CMR.

Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions (Part C) (p. 148)

UHG believes that this new HEDIS measure relies on data that will be difficult to obtain, making it a less effective measure of quality. Under the current system, there is no requirement for emergency departments (ED) to provide discharge instructions to MA Plans. In addition, UHG currently encounters some hospitals that are unwilling to share discharge summaries from impatient stays, and we strongly suspect hospital refusals to share would occur more frequently with ED discharge instructions. Therefore, access to the pertinent data needed for this measure may be difficult to obtain. Finally, while we understand the intent of this measure is to ensure data transfer from ED to primary care provider for patient safety reasons, we believe this new measure puts MA Plans in the position of intermediary, instead of holding hospitals accountable for care coordination and information sharing.

<u>Recommendation</u>:
For the reasons above, UHG recommends that CMS not proceed with this measure.

Polypharmacy Measures (Part D) (p. 151)

UHG supports CMS's proposal to begin reporting the Poly-ACH measure in the Patient Safety reports for the 2018 measurement year. However, UHG respectfully asks CMS to reconsider adding it to the Display or Star Rating measures.

There is a potential overlap in medications between the HRM measure, the polypharmacy Measure: Use of Multiple Anticholinergic (ACH) Medications in Older Adults measure, and the Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS) measure. If two or more of these become Star Rating measures, MA Plans may be penalized more than once for the same clinical concern.

Some of the medications included in this measure are also protected class medications (e.g., Antipsychotics, Antidepressants), which makes it difficult for Part D Sponsors to manage. In addition, the lists of medications included in this measure are commonly, and appropriately, used by many Medicare beneficiaries. For example, beneficiaries may be on an antidepressant (e.g., Paxil) and an Antimuscarinic for urinary incontinence. UHG is concerned that these measures may result in beneficiaries having reduced access to medically necessary medications because providers may not prescribe them as a result of these measures. UHG believes that management of these medications is best handled as outliers via Patient Safety reports, as opposed to becoming a Display measure and subsequent Star Rating measure.

Finally, concurrent use of anticholinergic therapy is defined as overlapping days for 30 or more (cumulative) days for two or more anticholinergic medications. If CMS is considering this as a Display or Star Rating measure, UHG respectfully requests that CMS reconsider the drug list to ensure it is clinically appropriate, and also consider increasing the overlap of concurrent therapy to 90 or more days to ensure that only beneficiaries who are on concurrent medications long term are identified as outliers for the numerator.

Recommendation:
UHG respectfully asks CMS reconsider adding polypharmacy measures to the Display page or making them Star Rating measures. . To the extent CMS disagrees, UHG requests that:

- CMS consider making only one of the polypharmacy or HRM measures a Star Rating measure.
- Review the drug list for the measure to ensure it is clinically appropriate in the Medicare population.
- Consider increasing the overlap of concurrent therapy to 90 or more days (if the polypharmacy measures are selected) to ensure that only beneficiaries who are on the concurrent medications long term are identified as outliers for the numerator.

Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS) (p. 152)

UHG supports CMS's proposal to begin reporting the Poly-CNS measure in the Patient Safety reports for the 2018 measurement year. However, UHG respectfully asks CMS to reconsider adding it as a Display or Star Rating measure.

As CMS acknowledges, there is a potential overlap in medications between the HRM measure, the Polypharmacy: Use of Multiple Anticholinergic (ACH) Medications in Older Adults measure, Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS) measure, and Polypharmacy: Concurrent Use of Opioids and Benzodiazepines measure. If CMS makes two or more of these measures Star Rating measures, there is a potential for MA Plans to be penalized more than once for the same clinical concern.

Some of the medications included in this measure are protected class medications (e.g., Antipsychotics, Selective Serotonin Reuptake Inhibitors, and Tricyclic Antidepressants), which makes it difficult for MA Plans to manage. In addition, the lists of medications included in this measure are commonly prescribed to Medicare beneficiaries for mental health needs. While UHG agrees that beneficiaries should not be on three or more concurrent CNS drugs, we are concerned that beneficiaries may be restricted access to medications that may be medically necessary and this measure may supersede clinical judgement. UHG

believes that management of these medications is best handled as outliers via Patient Safety reports, as opposed to becoming a Display measure and subsequent Star Rating measure.

Finally, concurrent use of CNS active medications is defined as overlapping days for 30 or more (cumulative) days for three or more CNS active medications. If CMS is considering this as a Star Rating measure, UHG respectfully asks that CMS reconsider the drug list to ensure it is clinically appropriate and also consider increasing the overlap of concurrent therapy to 90 or more days to ensure that only beneficiaries who are on concurrent medications long term are identified as outliers for the numerator.

Recommendation:
UHG respectfully asks CMS reconsider adding this as a Display measure, or making it a Star Rating measure. To the extent CMS disagrees, UHG requests that:

- CMS consider making only one of the polypharmacy or HRM measures a Star Rating measure.
- Review the drug list for the measure to ensure it is clinically appropriate in the Medicare population.
- Consider increasing the overlap of concurrent therapy to 90 or more days (if the polypharmacy measures are selected) to ensure that only beneficiaries who are on the concurrent medications long term are identified as outliers for the numerator.

Concurrent Use of Opioids and Benzodiazepines (p. 153)

UHG shares CMS's concerns around duplicative efforts with the OMS program that identifies potential opioid over utilizers who are also receiving a benzodiazepine. Concurrent opioid and benzodiazepine utilization is being addressed during case management. We also agree that a proportion of the concurrent opioid and benzodiazepine users will already be identified within the Poly-CNS measure, hence penalizing MA Plans twice for the same concern.

Recommendation:
UHG recommends that CMS not add the new PQA measure, Concurrent Use of Opioids and Benzodiazepines, to the Patient Safety reports, the Display page or as Star Ratings.

Additional PQA Medication Adherence Measures (Part D) (p. 154)

UHG supports CMS's consideration to not add the ADH-NWOA and ADH-MS adherence measures to the Patient Safety reports, the Display page, or Star Ratings.

Medicare Plan Finder Civil Monetary Penalty (CMP) Icon or Other Type of Notice (p. 164)

UHG acknowledges the intent behind CMS's proposal to display an icon or other type of notice on Plan Finder for MA Plans that have received a CMP. However, UHG is concerned that indicating an MA Plan has received a CMP without additional information may create confusion for beneficiaries and not accurately represent end-to-end MA Plan performance. For example, the icon may unnecessarily alarm a beneficiary for an issue that had relatively minor beneficiary impact. Furthermore, MA Plans in program audits are more likely to be penalized during the year of their audit, creating a cycle for plans with an icon, then no icon—without meaningfully informing beneficiaries about the plan's compliance with CMS's requirements.

UHG requests CMS:

- Clarify the "general information about a CMP" that CMS will provide via the "icon or notice".
- Allow MA Plans an opportunity to review in advance any information CMS intends to provide related to the CMP.
- Clarify the timeframes (frequency and duration) for posting the icons or notices.
- Consider not posting CMS Program Audit related CMP icons until a final report is issued, and remove them following completion of validation of any audit conditions that are the basis of the CMP. For all CMP types, UHG recommends that the icon not be posted longer than one year from date of issuance.

Audit of Sponsoring Organization's Compliance Program Effectiveness (p. 165)

UHG supports CMS's proposal to allow MA Plans that have had a program audit to treat it as meeting the annual compliance program audit requirement for one year from the date of the CMS program audit. UHG agrees that this will reduce an MA Plan's burden and allow time to implement appropriate corrective actions in response to the CMS audit and monitor implementation of those corrective actions to ensure they are effective.

Recommendation:
UHG requests clarification on when the one year timeframe starts and recommends that it begin when CMS issues the final audit report.

Section II – Part C (p. 168)

Meaningful Difference (Substantially Duplicative Plan Offerings) (p. 170)

UHG supports CMS's proposal to eliminate the meaningful difference requirements for MA Plan bid submissions starting with contract year 2019. We believe that Medicare beneficiaries will remain protected from discriminatory MA Plan benefit packages and still have a variety of different MA Plan options.

Total Beneficiary Cost (TBC) (p. 173)

CMS requests feedback on eliminating the current TBC evaluation in future years. UHG supports the removal of the TBC evaluation due to limitations with the current out-of-pocket cost (OOPC) tool and believes that an alternative test to measure the change in MA Plan benefits from one year to the next is not necessary because of the beneficiary protections already in place. In addition, if the TBC evaluation is removed, CMS should not require MA Plans to make changes to benefits due to year over year benefit cuts during desk review, as this would lead to an unfair competitive environment.

There are calculations within the current TBC test that limit the effectiveness of the evaluation. For example, the current TBC test does not factor in the impact of risk model changes or changes in the Health Insurers Tax. In addition, when new drugs are added to the formulary that may be better for the beneficiary, plans are penalized for removing the old drug that may be less effective for the beneficiary.

An alternative test is not necessary because beneficiaries are protected by the Medical Loss Ratio (MLR) rules as well as natural competition. MLR rules protect the beneficiary by requiring an actual minimum

loss ratio. Also, beneficiaries have the opportunity to annually select the MA Plan that best suits their needs. If a beneficiary is unhappy with the benefit changes from one year to the next, the beneficiary has the option to choose another plan.

Recommendation:
UHG supports the removal of the TBC evaluation in future years and believes that an alternative test to measure the change in MA Plan benefits from one year to the next is not necessary.

Health Related Supplemental Benefits (p. 182)

UHG supports CMS's proposal to expand the scope of the primarily health related supplemental benefit standard. Under CMS's expanded interpretation, in order for a service or item to be "primarily health related," it must diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization." UHG agrees that this expanded definition will allow MA Plans greater flexibility to offer supplemental benefits that can enhance beneficiaries' quality of life and improve health outcomes.

Medicare Advantage (MA) Uniformity Flexibility (p. 184)

As in response to CY2019 Proposed Rule, we support CMS's proposal to expand its interpretation of the uniformity of benefits requirement to permit MA Plans the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and lower deductibles for enrollees who meet specific medical criteria.

Recommendation:
We recommend that CMS allow MA Plans the ability to communicate information on these tailored benefits to all beneficiaries, as is required for all filed MA Plan benefits and cost sharing. CMS should not restrict communications to only those enrollees who have a targeted condition, as is currently required under the Value-Based Insurance Design (VBID) program. Restricting MA Plan benefit details would result in additional costs, complexity and confusion for providers, MA Plans and beneficiaries. In addition, beneficiaries with a condition not yet recorded by the MA Plan may avoid or delay obtaining needed services to avoid anticipated out-of-pocket costs associated with those services, rather than obtaining them under the enhanced condition-specific benefits and lower cost sharing for which they are eligible under the MA Plan.

In addition, while UHG supports CMS's proposal to expand the scope of the primarily health related supplemental benefit standard, we also request CMS consider allowing additional types of flexibility:

- CMS should allow MA Plans flexibility to authorize and pay for services not directly covered under the MA Plan for specific individual beneficiaries without making those same services uniformly available to every beneficiary with a specific diagnosis. For example, an MA Plan may authorize transportation on a MA Plan without a transportation benefit for particular beneficiaries who have been missing medical appointments and as a result, may end up hospitalized. Providing transportation in those circumstances could help avoid hospitalization and ensure the best medical outcome for that individual. Similarly, allowing MA Plans to offer home based services for specific beneficiaries who are at risk for decline if taken out of their home (such as those with dementia) will result in better outcomes and potentially lower costs.

In short, providing MA Plans the flexibility to do the right thing for each individual beneficiary will enable MA Plans to achieve the best quality and clinical outcomes for beneficiaries.

- CMS should allow reduced cost sharing for certain covered benefits, specific tailored supplemental benefits and/or lower deductibles for beneficiaries who participate in disease management or related programs, as allowed under VBID, before the end of the VBID demonstration. This would allow MA Plans to provide an incentive for vulnerable beneficiaries to be more engaged in managing their chronic medical conditions, resulting in better health outcomes for them.

Reward and Incentives for Completion of Health Risk Assessment (HRA) (p. 186)

UHG supports CMS's proposal to include the completion of an HRA as a permitted health-related activity in a Rewards and Incentives Program.

Improving Beneficiary Communications and Reducing Burden for Integrated DSNPs (p. 187)

UHG supports CMS's efforts to work with states on greater integration and coordination of DSNP products. UHG encourages efforts that will result in eliminating conflicting regulatory requirements.

Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) (p. 188)

The ANOC portion of this provision does not reflect the language in the CY2019 Proposed Rule that grants MA Plans the flexibility to provide the EOC electronically and allows the EOC/Directories/ Formulary to be provided by October 15. We fully support the CY2019 Proposed Rule and encourage CMS to allow MA Plans to provide the EOC electronically and the EOC/Directories/Formulary by October 15 for the 2019 ANOC mailing.

D-SNP Non-Renewals (p. 189)

CMS requires MA Plans that are non-renewing contracts, plan benefit packages, or reducing their service areas to notify their beneficiaries at least 90 days before the end of the current contract period and provide information about alternative enrollment options. CMS requires that MA Plans use the Non-Renewal Model Notices provided by CMS and submit them in the Health Plan Management System (HPMS). MA Plans must also input actual mail dates and the number of impacted beneficiaries into HPMS.

Over the last several years, CMS has released the SAR model toward the end of September (e.g., September 21, 2016, September 20, 2017), making it challenging for MA Plans to meet the SAR/NR beneficiary notification deadline. This late release impacts the ability of MA Plans to create the notices, conduct internal quality assurance to confirm the accuracy of the notices, and then send the personalized beneficiary notices in time to meet SAR deadlines. It will be especially challenging if CMS makes changes to any of these notices from the prior year model notice.

<u>Recommendation</u>:
UHG is supportive of the new integrated SAR. Additionally, in order to ensure that MA Plans are able to produce and mail notices timely, we strongly recommend that CMS release the annual SAR/NR guidance and model letters with other CMS-required model documents no later than April 2018. We also request that CMS issue the SAR alternative plan information to be populated in the notices by the end of August.

This will help ensure that MA Plans have sufficient time to: (1) conduct meaningful quality assurance to ensure that accurate information is provided to beneficiaries and (2) meet the SAR/NR deadline so that beneficiaries receive their notices, Medigap rights, and alternative plan information in time to make an informed decision regarding their next year's coverage needs.

Additionally, within the CMS NR and SAR Guidance and Enrollee Notification Models, CMS notes, "Many other States have Medigap protections that go beyond federal requirements. The State-specific information can be obtained by contacting your local SHIP office or State Department of Insurance."

Based on potential challenges in trying to obtain this information to develop MA Plans' state-specific notices, and to ensure that the language in the Medigap notices is consistent across MA Plans, we believe that CMS should either:

- Provide the State-specific Medigap notices to MA Plans for all states that have special requirements beyond the federal requirements (as CMS already does for Massachusetts, Minnesota, and Wisconsin) OR
- Include standard language in the model general Medigap document, What You Should Know About Medigap (Tab F). Under the section Get Help Comparing Your Options, there is language that currently states, "Call <Name of SHIP> at <SHIP Phone>. Counselors are available to answer your questions, discuss your needs, and give you information about your options and Medigap policies. All counseling is free. TTY users should call <SHIP TTY>." We recommend that CMS add a statement to this section that says, "Your state may have additional Medigap requirements. To find out, call your SHIP office."

Encounter Data Listening Forums, Monitoring and Compliance Activities (p. 191)

CMS proposes to continue holding listening forums in 2018 and again reach out to MA Plans to participate. CMS states that the listening forums have helped to highlight areas in the encounter data submission process where both MA Plans and CMS can make improvements. CMS's priority continues to be ensuring the completeness and accuracy of encounter data submissions and to seek stakeholder feedback. Such feedback has indicated support of CMS's framework for monitoring and compliance activity focused on operational, completeness and accuracy performance, but also suggested to CMS that it should adopt an incremental approach for monitoring and compliance activity thus, CMS continues to outreach for stakeholder feedback in this area. CMS is reviewing comments to its November 1, 2017, HPMS memo "CMS Monitoring and Compliance of Encounter Data, Performance Metrics and Thresholds – For Comment", and states that it will finalize the performance and monitoring metrics and thresholds in an HPMS memo to be communicated in early 2018.

UHG actively participated in the CMS listening forums and found them valuable. We agree with and support CMS's recommendation to continue the sessions in 2018.

With respect to CMS's three performance monitoring focus areas (e.g., operational, completeness, accuracy), UHG has no concerns with the operational and accuracy categories. However, as noted in our response to the November 2017 HPMS memo, "CMS Monitoring and Compliance of Encounter Data, Performance Metrics and Thresholds – For Comment", UHG shared its feedback regarding three completeness measures: Compliance Performance measures Extremely Low Volume of Inpatient/Professional/Outpatient Encounter Data Records (C2/C3/C4). UHG stated that comparing RAPS to EDS may be challenging, as the provider type reported on RAPS may not have been derived with

the same filtering logic utilized by CMS for EDS. Additionally, CMS is imposing Medicare FFS edits resulting in certain EDS transactions being rejected. The Medicare FFS edits also resulted in in our inability to have all encounter data submissions accepted by CMS. UHG and other 2017 listening session participants subsequently provided examples of how the provider type in RAPS does not align with how CMS views the data in EDS. We believe this will continue to yield "false" results when CMS is trying to measure completeness based on provider type submissions between RAPS and EDS.

UHG welcomes the opportunity to provide feedback to CMS via listening sessions and direct meetings. We believe the ongoing open dialogue will drive to completeness and accuracy of encounter data submissions by MA Plans.

Section III – Part D

Changes for CY 2019 Formulary Submissions (p. 193)

CY 2019 Formulary Reference File (p. 193)

UHG supports CMS removing drugs (e.g., RxCUIs) from the CY 2019 Formulary Reference File (FRF) that have low utilization and/or are more commonly covered under Medicare Part B. However, UHG encourages CMS to not make any changes to the FRF after Part D Sponsors finalize their formulary submissions for CY 2019. As CMS is likely aware, mid-year changes are confusing and disruptive to beneficiaries, as well as Part D Sponsors' formulary processes. For example, in the CY2018 January submission full FRF, CMS made 29 RxCUI updates that resulted in those RxCUIs referring to different products, even though CMS did not delete the legacy RxCUI and a new RxCUI was added (in certain instances the label name and product changed, and in other instances the product changed, but not the label name). UHG made formulary decisions based on the legacy RxCUIs and had already obtained CMS approval for those decisions. As a result, UHG had to revise its formulary to add new drugs that were not previously contemplated in our bid. In order to avoid this type of unintended consequence to the Part D Sponsor and any related beneficiary disruption and confusion, UHG recommends that CMS not make a change of this nature mid-plan year. UHG also recommends that CMS adopt a methodology of making RxCUI changes to different products that requires the deletion of the legacy proxy product and the addition of a new RxCUI. This methodology will allow Part D Sponsors to submit decisions for the updated products that fall under the new RxCUI. In addition, UHG recommends that proxy NDCs only be changed when those NDCs become obsolete or are no longer Part D eligible.

UHG appreciates the opportunity to provide comment on the optimal submission window for the summer formulary update. UHG understands the balance that CMS is hoping to achieve by providing sufficient time for additional formulary substitution, while also giving Part D Sponsors enough time to finalize formulary documents for printing. UHG believes that the existing summer update submission window at the end of July strikes exactly the balance that CMS is seeking. CMS indicates that it is considering extending the update submission window into August so that formularies can include newly approved brands and generics that occur in July and into August. However, the reality is that the number of formulary substitutions that might be added during an extended submission window is minimal. Given that the opportunity for formulary substitutions is low, and the need to ensure accurate and complete formulary documents is high, UHG recommends that CMS not make any changes to the submission window and that it continue to close the last week of July.

UHG also recommends that CMS build enough time into the formulary submission process to ensure that the current year FRF and Change Reports are taken into consideration for those RxCUIs/drugs that are included in the Stage 4 Change Report for the future year, so that the drug lists align with the summer updates. This will help ensure a better beneficiary experience, it will decrease the number of questions to Part D Sponsors on why certain drugs are not listed in future year materials, and it will decrease the size of the first Change Report in the next calendar year.

Finally, UHG respectfully disagrees with CMS's proposals for changes to the timing of the updates to the MPF and 2019 FRF. UHG is concerned that the proposals will not allow Part D Sponsors enough time to incorporate those changes in materials, annual readiness activities, etc., in advance of January 1.

Additional Demonstration Drug (ADD) File (p. 195)

UHG supports CMS's proposal to have the ADD Validation File available via HPMS in advance of the ADD File submission deadline of June 8, 2018, and requests that the availability of the ADD Validation File be recorded in the Annual Calendar for Section I – Parts C and D of the 2019 Call Letter.

Non-Extended Day Supply (NDS) File (p. 195)

UHG supports CMS eliminating the Non-Extended Day Supply (NDS) supplemental file submission for formularies that offer partial extended day supply coverage for at least one tier. UHG understands that it will need to continue to identify in the plan benefit package if there are any drugs for which it 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. We request confirmation that Part D Sponsors are still required to identify in formulary materials, posted or published, if there are any drugs with a limit of a one month supply if the drugs are included on a tier that is otherwise available at an extended day supply.

Over-the-Counter (OTC) Validation File (p. 196)

UHG supports CMS's efforts to reduce the burden on Part D Sponsors as it relates to the creation and submission of OTC supplemental files. CMS's proposal, to provide Part D Sponsors with an OTC reference file for CY2019 that uses a proxy code (e.g., RXCUI), raises a number of questions about the timing of the release of the draft OTC reference file, the file layout, and the content (i.e., NDC and/or RXCUI).

Recommendation:
Given the number of changes that Part D Sponsors may be expected to make to their file submission in order to align with CMS's OTC reference file, UHG strongly recommends that CMS provide Part D Sponsors with information about the OTC file as it becomes available, to allow time for Part D Sponsors to make any necessary changes or adjustments in advance of the supplemental file submission deadline. If CMS will be issuing an OTC reference/validation file, we recommend that the file be issued once per year prior to the upcoming plan year and prior to the formulary submission window.

CMS indicated it will provide an opportunity to review a draft version of the OTC Validation file. UHG requests that CMS provide more information about this file such as the timing, file layout, whether the file will include only an RXCUI or if it will include an associated NDC. It would be most helpful to include which NDC is related to which OTC RxCUI and for a specific time period (e.g., Start/End Dates). UHG also requests that CMS clarify whether any OTC Proxy Equivalents will be introduced to this process.

Specialty Tiers (p. 201)

UHG agrees with exempting the formulary tier in which Part D Sponsors place very high cost and unique items ("specialty tier") from its tiering exception process. However, UHG reiterates its concerns with the proposed changes to Part D Tiering Exceptions in the CY2019 Proposed Rule. UHG urges CMS to reconsider its proposal that would allow, in certain circumstances, drugs in a non-preferred tier to move to a specialty tier status if the cost-sharing of the specialty tier is more preferable. Only beneficiaries in Part D Sponsors' plans where the tiers have coinsurance will benefit from allowing a drug an exception to a specialty tier status. Not all beneficiaries have a Part D plan where the cost share is a coinsurance, as opposed to a flat co-pay. UHG believes that this change will result in beneficiary inequity and should not be permitted.

In addition, as CMS notes, tiering composition varies across Part D Sponsors, especially given the increase in generic tiers. Accordingly, determining the appropriate exception tier and cost share can vary as well. UHG recommends CMS establish clear and consistent rules for determining the exception tier and related cost share. When assigning a drug to the lowest applicable cost sharing associated with tiers that contain both brand and generics, UHG proposes that CMS allow Part D Sponsors to assign the cost sharing for the highest alternative tier, even if that tier contains a drug that the beneficiary has tried and failed so long as the lower tiers do not contain any other alternatives for the beneficiaries. For example, if a tier 4 generic drug is used for diabetes, and tiers 1 and 3 contain alternatives that the beneficiary has tried and failed, yet tier 2 does not contain any alternatives for diabetes, then the appropriate assigned cost share would be the cost share associated with tier 3.

Finally, UHG would appreciate additional guidance from CMS on what constitutes an alternative drug for purposes of tiering exceptions. CMS indicates that it refers to a preferred or formulary drug for treatment of the same condition "as it affects the enrollee—that is taking into consideration the individual's overall clinical condition…." However, UHG believes additional clarification is needed and that CMS should specify that a drug is only considered an alternative drug if it has the same route of administration and the same therapeutic classification as the requested drug. For example, if a request is for a generic oral antipsychotic and the lower tiers contain only injectable antipsychotics, the injectable antipsychotics are not clinically appropriate alternatives to an oral antipsychotic, therefore the oral antipsychotic is ineligible for reduction to the tier of the injectable antipsychotics.

Improving Drug Utilization Review Controls in Medicare Part D (p. 202)

UHG supports CMS's efforts to address the growing national opioid epidemic, including moving toward alignment with the Centers for Disease Control Guideline for Prescribing Opioids for Chronic Pain (CDC Guidelines). It is important to note that while UHG supports CMS providing Part D Sponsors with more tools to combat the opioid epidemic, the purpose of the CDC Guidelines is to assist primary care providers in delivering safer, more effective chronic pain management. Prescribers are at the forefront of prescribing for Medicare beneficiaries, and they have clinical insight into the beneficiary's condition that is not readily visible to Part D Sponsors. With that in mind, UHG continues to be supportive of CMS's efforts to decrease the overutilization of opioids, and asks that CMS take a more flexible approach in allowing Part D Sponsors the ability to implement meaningful programs in an effort to decrease opioid overutilization while caring for the Part D Sponsor's at risk beneficiaries.

UHG also encourages CMS to address some of the other issues that arise as Part D Sponsors limit access to opioids. Changes to opioid-related policies will likely lead to increased beneficiary confusion,

dissatisfaction, complaints to Medicare (CTMs), and grievances. In order to address these factors, UHG has two suggestions. First, that CMS require prescribers to provide written evidence that demonstrates an opioid is medically necessary for the beneficiary and uphold decisions to deny coverage for an opioid when the evidence is insufficient. Second, CMS should acknowledge that these policy changes will likely increase beneficiary complaints that will be reflected in CTMs and Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys. CMS should hold Part D Sponsors harmless for good faith efforts to address inappropriate opioid prescribing and use.

Retrospective DUR - Opioid Potentiator Drugs (p. 205)

UHG recognizes that there are a number of drugs that place beneficiaries at greater risk for adverse events when taken concomitantly with opioids. As the focus on opioid use is intensifying, prescribers and patients may be looking for non-opioid alternatives in the treatment of chronic pain. These alternatives could include transitioning from an opioid to a non-opioid drug, maintaining the lowest effective dose of an opioid, while concurrently prescribing a non-opioid for the treatment of a chronic condition (i.e., gabapentin/pregabalin). There are many compendia-approved indications for both gabapentin and pregabalin, and although prescribing these medications concomitantly may be of concern, it is not a contraindication.

Enhancing the OMS by adding additional flags to high risk beneficiaries who use “potentiator” drugs (such as gabapentin and pregabalin) in combination with prescription opioids may prompt discussion with providers; however, based on UHG’s outreach experience with providers for concurrent prescribing of benzodiazepines and opioids, it may not significantly change prescribing practices. Prescriber engagement and collaboration is necessary in order to appropriately address potential opioid overutilization. UHG is concerned prescribers will become overwhelmed by Part D Sponsor outreach to discuss drug classes that may place beneficiaries at risk for adverse events (such as opioids, potentiators, benzodiazepines), and prescribers may become unresponsive.

If CMS moves forward with adding potentiator drugs to the OMS, in order to better focus prescriber outreach and case management, UHG recommends adding a flag for potentiator drugs only in instances when beneficiaries meet the existing overutilization criteria, and are concomitantly receiving very high doses of potentiator drugs (> 2400 mg of gabapentin). This would target beneficiaries at the highest risk for adverse events, while minimizing unnecessary outreach to prescribers who may be transitioning from an opioid to a non-opioid, or attempting to minimize increasing the opioid dosage by adding a non-opioid alternative to a beneficiary's regimen.

UHG requests further clarification on whether potentiator drugs should be included in the Part D Sponsor’s identification criteria during the initial targeting so that conversations are held with prescribers during the initial case management outreach, versus adding a flag to the OMS and having to engage prescribers after the quarterly OMS reports are received. Clarification is also needed on whether CMS will require Part D Sponsors to provide responses (i.e., response codes) reporting back the results of addressing the concurrent utilization during case management. If yes, Part D Sponsors need to know when this will become effective, as program and system enhancements may be required to support the OMS response process for these additional classes of drugs.

<u>Recommendation</u>:
In order to balance the need to target the highest risk beneficiaries with minimizing unnecessary outreach to prescribers, UHG recommends adding a flag for potentiator drugs only in instances when

beneficiaries meet the existing overutilization criteria, and are concomitantly receiving very high doses of potentiator drugs (> 2400 mg of gabapentin). UHG also recommends that CMS clarify its proposal by responding to the questions above.

Concurrent DUR (p. 207)

MME Safety Edits for High, Chronic Prescription Opioid Users

UHG appreciates CMS's desire to align with the CDC guidelines, which recommend prescribers generally avoid increasing the daily dosage of opioids to 90 MME. However, UHG has concerns with CMS's expectations that all Part D Sponsors should implement a hard edit that is triggered when a beneficiary's cumulative daily MME reaches or exceeds 90mg starting in plan year 2019. Rather, UHG supports an individualized policy that permits Part D Sponsors flexibility to modify MME thresholds to account for their member mix and other circumstances. UHG believes that a 90 MME limit, if implemented as proposed, would be highly disruptive, administratively burdensome, and too easily overridden by prescribers.

Notably, a 90 MME hard edit would significantly increase the administrative burden on Part D Sponsors (including coverage exception/appeal volumes), with limited impact on opioid overutilization. In UHG's experience with the cumulative MME safety edit, beneficiaries who receive a rejection at the point-of-sale (POS) and undergo a coverage review are able to easily receive the prescribed quantities of opioids. Current CMS guidance requires Part D Sponsors to approve a coverage determination request if a prescriber simply attests to the opioid utilization, but does not provide any supporting medical documentation. This has led to high approval and low denial rates in 2017. In January 2018, 84% of our exception requests related to the MME safety edit were approved, and only 15% were denied. Without first revising the exception process, UHG expects this approval rate to remain high even if more restrictive dosing limits are applied. An edit applied at the POS under the current exceptions process may be providing awareness to prescribers of the high dose of opioids being dispensed to their patients, but it does not appear to stop the prescriber from attesting to the high dose.

Recommendation MME Threshold:
UHG strongly urges CMS afford Part D Sponsors the opportunity to tailor the MME threshold based on their own member population and utilization patterns, and continue to allow Part D Sponsors the flexibility to modify the threshold if and when appropriate by submitting changes through HPMS. This will allow Part D Sponsors flexibility, while at the same time giving CMS insight and continued visibility to the threshold being employed by the Part D Sponsors.

Making significant changes to the MME safety edit without knowing whether the concurrent edit is effectively managing overutilization places significant burden on Part D Sponsors who will be working and focusing efforts to prepare for the implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA). Therefore, UHG respectfully requests that CMS review and analyze 2017 Part D reporting as it relates to MME POS edits before making additional changes to the Concurrent DUR guidance.
If CMS makes the decision to mandate a hard edit at 90 MME, UHG strongly urges CMS to:

- Consider a phased-in approach through plan year 2020 allowing Part D sponsors time to assess strategies that would best support appropriate member and provider notifications outside of formulary materials.

- Provide Part D Sponsors support with implementing a broader provider and member communication and notification process that would provide greater visibility of opioid management requirements and Part D Sponsor responsibility to comply with such requirements.
- Require providers to provide written evidence that demonstrates an opioid is medically necessary for the beneficiary and uphold decisions to deny coverage for an opioid when the evidence is insufficient.
- Hold Part D Sponsors harmless for CTMs related to good faith efforts to control egregious opioid utilization.
- Consider exempting beneficiaries with high opioid utilization from receiving CAHPS surveys.

Recommendation 7 Day Supply:
While UHG supports CMS's efforts to better manage opioid overutilization in the Part D program, UHG opposes CMS's proposal for a 7 days' supply for the MME safety edit. The proposal for a 7 days' supply is intended to balance beneficiary access and reduce the potential for any unintended consequences; however, the 7 day limitation will be highly disruptive, confusing, and burdensome for both beneficiaries and providers, and will most certainly generate complaints. Also, implementation of the 7 days' supply would be operationally challenging, requiring system enhancements to ensure appropriate administration of the MME edit.
UHG recommends that if a 7-day limit is mandated after a POS rejection is triggered, that each prescription should be filled with a 7 day supply versus requiring a pharmacist to determine which prescription should take precedence. If CMS moves forward with the proposed 7 days' supply, UHG requests CMS also provide clarification on these questions:

- CMS proposes that the "7 days' supply is only available once after the 90 MME hard edit is triggered during a specific time period". What is the "time period" proposed by CMS? Is "the time period" defined as the plan year?
- In instances when multiple prescriptions are submitted at the same time, the burden will fall on the pharmacist to assess the immediate needs of the beneficiary to help determine which prescription should be filled for a 7 days' supply. Is a total of a 7 day supply of both opioids allowed when 2 prescriptions are presented at the same time? (i.e., 2 prescriptions are presented: the pharmacist fills a 3 day supply of one opioid prescription and a 4 day supply of the other). Assessing the immediate needs of the beneficiary to determine which of 2 prescriptions should be filled for the 7 days' supply is a significant burden to place on dispensing pharmacists.
- UHG has concerns that Part D Sponsors may not be able to ensure that the beneficiary only receives a 1-time fill for the 7 days' supply. The beneficiary could conceivably go to multiple pharmacies, trigger the MME edit and receive a 7-day fill, and then go to another pharmacy to repeat the process. UHG requests guidance regarding how to feasibly ensure that Part D Sponsors can monitor/flag this one-time fill?
- UHG would also appreciate CMS's clarification on transition fill requirements and level of care changes for the MME edit with the 7 day allowance. Will the 7 day allowance be considered a transition fill rendering the member ineligible for a 30 day transition fill?
- What is the expectation for the reject code that is generated for the 7 day fill?
- UHG requests clarification from CMS on buprenorphine product inclusion in the MME edit specifications. Buprenorphine products for medication assisted therapy (MAT) should not be included within the edit specifications. However, can Part D Sponsors include buprenorphine products indicated for the treatment of pain (i.e., Butrans and Belbuca) within the edit

specifications? How will CMS ensure that Part D Sponsors are not negatively impacted by beneficiary complaints due to this change? UHG recommends CMS clarify that complaints about the 7 days' supply will not lower a Part D Sponsor's quality ratings.

Concurrent DUR: Days Supply Limits for Opioid Naïve Patients (p. 212)

UHG supports CMS's proposal to limit the initial amount of prescription opioids dispensed for opioid naïve beneficiaries to 7 days with a daily dose maximum of 50 MME in order to reduce the risk that beneficiaries develop an affinity for these drugs and transition to chronic use or misuse. While this change aligns with UHG's broader prevention strategy, UHG requests additional clarification on the proposed guidance:

- UHG requests that CMS define "initial opioid prescription fill" for opioid naïve patients. What process should Part D Sponsors use to determine that the prescription is an "initial opioid prescription" for an opioid naive beneficiary to avoid compromising appropriate pain treatment for beneficiaries who may not be opioid naïve (i.e., a newly enrolled beneficiary)?
- While there may be ways to potentially identify current beneficiaries who are opioid naive, Part D Sponsors do not have the ability to identify whether the opioid is being prescribed for "acute pain" at the POS. How should Part D Sponsors identify prescribing for an acute indication?
- How will transition and level of care guidance apply within the scope of the 7 day supply limits with a 50 MME max daily dose for opioid naive beneficiaries in conjunction with CMS filed individual opioid quantity limits that are transition eligible? What takes precedence -- the quantity limit or the 7 day supply limit?
- UHG also requests that CMS provide specific guidance as to how additional fills beyond the "initial fill" of a 7 days' supply be handled. If the intent is to require review through the coverage determination process, what criteria should be used to allow exceptions to the 7 day limit? If it is CMS's intent is to require a coverage review for all beneficiaries who require additional quantities (greater than a 7 day) after the initial fill, UHG suggests Part D Sponsors be allowed the flexibility to determine if a coverage review will be conducted after the initial 7 day fill is exhausted and additional quantity is needed, or if two 7 day fills will be allowed before a coverage review is undertaken. This will allow Part D Sponsors to minimize the volume of cases undergoing a coverage review in instances where opioid naive patients may require more than one "initial fill" of a 7 day supply for acute pain (i.e., prolonged post-surgical pain). Also, as these requests are reviewed through the coverage determination process, will Part D Sponsors allow a short term approval (for acute conditions), in order to minimize the transition to chronic use, or will Part D Sponsors continue to be required to approve an exception and have it be valid through the remainder of the plan year?
- How should Part D Sponsors submit 7 day limits to CMS for the purposes of formulary submissions?

Recommendation:
UHG recommends that CMS consider this to be a concurrent DUR (cDUR) edit, reject 88 and included within cDUR MEDLIMIT criteria with the following recommendations:

- Allow Part D Sponsors the flexibility to apply a 7-day fill limit with a daily dose maximum (i.e., 50 MME/day) with a cumulative hard reject of maximum 7 days' supply. This limit would only be applicable to those beneficiaries who are naive to therapy.

- Due to limitations of medical claims data, allow Part D Sponsors to align with the spirit of the CDC Guidelines by defining "acute pain" as a beneficiary who is new to therapy (i.e., has not had treatment in past 120 days).
- Applying the edit to only short acting opioid products to ensure beneficiaries established on long acting (LA) opioids are not affected by the 7 day limitation.
- Exclude Transmucosal Immediate Release Fentanyl (TIRF) drugs from the list, which are only indicated for break through cancer pain, as most Part D Sponsors have already managed these products through Prior Authorization.

Concurrent DUR: Opioid Duplicative Therapy Safety Edits (p. 213)

UHG appreciates that having additional DUR controls at the POS, like a soft edit, may potentially help reduce excess opioid supplies and reduce adverse events. However, UHG is apprehensive that multiple opioid POS edits could potentially generate a combination of messages, and that soft or hard rejects will likely cause significant confusion. Therefore, creating a hierarchy for opioid POS edit messaging will be necessary. UHG asks that CMS not require a soft POS edit for duplicative LA opioid therapy for January 1, 2019, but rather allow Part D Sponsors the flexibility to phase in implementation in order to allow time for any needed enhancements and testing. This will ensure POS messaging is appropriate based on all hard and soft edits.

UHG is also concerned that the number of hard and soft opioid edits being implemented may lead to frustration and noncompliance from clinicians at the POS, potentially giving all edits less value and meaning. If a duplicative safety edit is required, UHG recommends Part D Sponsors have the flexibility to implement this edit at the drug level (GPI 12), permitting beneficiaries to switch between doses and allow for seamless titration. UHG asks CMS clarify the definition of a "long-acting opioid," and whether there will be a list of these defined opioids, or if the Part D Sponsors would have the flexibility to define the drug lists and targeting to minimize disruption.

Recommendation:
UHG recommends that CMS allow Part D Sponsors to phase-in implementation and not require a soft POS edit for duplicative LA opioid therapy for January 1, 2019. In addition, UHG recommends that Part D Sponsors have flexibility to implement a duplicative safety edit, if required, at the drug level (GPI 12). UHG also recommends CMS clarify its proposal by responding to our questions above.

Concurrent DUR: Concurrent Use of Opioids and Benzodiazepines (p. 216)

As previously stated, UHG appreciates the advantages of having additional DUR controls at the POS; however, this should be balanced with the risk that multiple opioid POS edits could generate a combination of messages or rejects that may cause significant confusion.

In September 2017, the Federal Drug Administration (FDA) issued a drug safety communication alerting health care providers and patients of the increased risk of serious side effects when combining MAT drugs with benzodiazepines. While co-administration between MAT drugs (e.g., methadone and buprenorphine) and benzodiazepines or other CNS depressants may increase the possibility of harm, concomitant therapy with MAT may be appropriate in some patients. If concomitant use is necessary, careful management and monitoring is recommended. The FDA asked health care providers and patients to be aware of these risks, but at the same time, the agency also reinforced that MAT should not necessarily be denied to patients taking these other medications. The dangers associated with failing

to treat an opioid use disorder would outweigh the risks of co-prescribing MAT and benzodiazepines. For that reason, before moving forward with cDUR of opioids and benzodiazepines, UHG requests that CMS clarify if the opioid/benzodiazepine soft edit should be triggered when a member is concurrently receiving MAT and a benzodiazepine.

Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs (p. 218)

UHG appreciates CMS's recognition of the challenges that Part D Sponsors face in obtaining reliable information to determine whether immunosuppressants are covered under Part B or Part D. UHG supports streamlining the Part B vs. Part D coverage determination process, and has the following recommendations.

No Prior Part D Claims History for Immunosuppressants

CMS proposes that if a Part D Sponsor has not received information from CMS indicating that Medicare covered the transplant for the beneficiary or the Part D Sponsor does not have medical claims showing a history of a covered transplant and the Part D Sponsor has not previously received information from a prescriber that the transplant was covered by Medicare, CMS expects Part D Sponsors to default to covering the immunosuppressant under Part D. UHG does not agree with this approach.

UHG is concerned that defaulting coverage to Part D without verifying Medicare coverage of the transplant may cause beneficiary disruption, particularly if coverage of the immunosuppressant should be under the Part B benefit. For example, if a beneficiary is enrolled in a PDP plan and claims default to coverage under Part D due to a lack of prior claims history, and new information is received after the claim is submitted indicating coverage should be under Part B, beneficiaries would need to act quickly to obtain coverage through Part B, leading to a potential disruption in essential therapy.

Recommendation:
UHG agrees with CMS that obtaining and relying on a prescriber's assessment that the transplant is covered by Medicare is burdensome and not always accurate. Therefore, UHG recommends that instead of defaulting coverage to Part D, it allow Part D Sponsors to continue to reject immunosuppressants and perform a Part B versus D coverage determination based on MARx Medicare eligibility information and information on the date and type of transplant obtained from the prescriber. UHG believes that CMS (via MARx or otherwise) information, combined with the date and type of transplant, is the most accurate method to determine whether coverage is appropriate under Part B or D.

Prior Part D Claims History and MARx Currently Indicates that Medicare Covered the Transplant

CMS proposes that when a Part D Sponsor has covered drugs under Part D, and subsequently MARx is updated to indicate that Medicare covered the transplant, the Part D Sponsor must rely on the MARx information going forward and notify the beneficiary that the Part D Sponsor can no longer cover the immunosuppressant because it is covered under Medicare Part B. Part D Sponsors' current processes may not involve routine review of MARx after a Part B versus D determination has been made and an approval issued for the remainder of the plan year. Accordingly, UHG believes that CMS will need to establish a notification process to inform Part D Sponsors that MARx has been updated to indicate a

beneficiary has a Medicare covered transplant. UHG recommends that this notification include the date and type of transplant.

Inhalation Durable Medical Equipment (DME) Supply Drugs

CMS indicates that Part D Sponsors can rely on a patient residence code of "3" or "9" (Nursing facility and Intermediate Care Facility, respectively) on a pharmacy claim for determining when such inhalation drugs may be covered under Part D. Patient residence codes are submitted by pharmacies, on behalf of beneficiaries, for claim processing by Pharmacy Benefit Managers. Because beneficiaries living in an Assisted Living Facility (ALF) likely obtain their nebulizer inhalation solutions from an long term care (LTC) provider and subsequently have these medications administered by clinical staff (as in a LTC facility), UHG recommends that CMS also consider patient residence code 4 (Assisted Living Facility) in defining an LTC facility for purposes of Part D coverage of nebulizer inhalation solutions.

Part D Mail-Order Refill Consent Policy (p. 220)

UHG supports CMS modifying its existing mail order refill consent policy. UHG believes that auto-ship/refill programs offered by mail order pharmacies create value and convenience for beneficiaries who take certain maintenance medications regularly and ultimately reduce costs. CMS is requesting data that would indicate actual improved adherence by beneficiaries resulting from automatic refills; however, UHG is not aware of any current studies that have been conducted that measure adherence as a direct result of receiving an automatic refill. Rather, numerous studies have been conducted that indicate that beneficiaries have better adherence when they use a mail order pharmacy instead of a retail pharmacy. UHG believes that it necessarily follows that if a beneficiary has access to mail order programs, including auto-refill programs, they will have better adherence to their medications. UHG offers the following to illustrate this point:

- A study published in the Journal of Managed Care & Specialty Pharmacy by OptumRx on patients who newly initiated treatment with any of 5 therapeutic medication classes (antidiabetics, betablockers, calcium channel blockers, other antihypertensives and statins) and also filled 90-day supply prescriptions, found that those patients using mail-order pharmacies appear to have better adherence to maintenance medications than patients filling 90-day supply at retail pharmacies.[1]
- In a study published in the Journal of Medical Economics by Prescription Solutions (now OptumRx) a review of data for Medicare Part D beneficiaries who newly initiated oral anti-diabetic treatment concluded that patients using mail-order pharmacy had better adherence to oral anti-diabetic medications than those who used retail pharmacies.[2]

UHG understands and shares in CMS's concern that auto-refill programs may increase waste and consequently create additional cost to beneficiaries or the Part D program. UHG's existing mail-order auto-refill program (for EGWPs) considers higher medication possession ratios when initiating auto-

[1] Journal of Managed Care & Specialty Pharmacy: Medication Adherence Amount Mail-order Pharmacy Users Versus Retail Pharmacy Users with 90-Day Supply Prescription Fills, 2015

[2] Journal of Medical Economics: Mail-order pharmacy use and medication adherence among Medicare Part D beneficiaries with diabetes (Prescription Solutions study), 2011

shipment of refills to address and prevent an oversupply to beneficiaries. However, to further combat the potential for waste and abuse, UHG recommends that CMS replace the affirmative consent requirement with a requirement that Part D Sponsors obtain a beneficiary's "opt-in" in order to auto-refill medications on file (and not on a per drug basis). If beneficiaries are allowed to "opt-in" to the mail-order auto-refill program, UHG also recommends that CMS eliminate any requirement that Part D Sponsors provide a full refund for returns of either unneeded or unwanted medications, regardless of whether the medications were partially or fully unused. In UHG's experience, the existing refund policy is often abused and leads to waste because returned refills are unable to be re-stocked at the mail order pharmacy. If beneficiaries are required to opt-in to the program and, as CMS suggests, receive a refill shipping reminder, they will have sufficient time and opportunity to cancel any unwanted or unneeded orders, and as such, Part D Sponsors should not be responsible for issuing a full refund on auto-refill returns. UHG believes this approach will address CMS's concerns that mail-order auto-refill programs increase waste and cost to beneficiaries and the Part D program.

In addition, UHG supports modifying the current condition of annual beneficiary confirmation and recommends that if beneficiaries opt-in to the mail-order auto-refill program, to disenroll from the program, beneficiaries must affirmatively opt-out. To avoid any beneficiary confusion, CMS could require Part D Sponsors to provide an annual notice to beneficiaries that describes the mail-order auto-refill program, along with instructions on how to opt-in/opt-out.

UHG also asks that if CMS modifies its current policy, it consider whether changes should be made to address continuity of treatment when there are no remaining refills and a new prescription is required and whether the new prescription should continue to be eligible for automatic delivery. UHG believes that if appropriate processes are in place to ensure dosage changes are properly managed, and prior dosages discontinued by the pharmacy, continuity of treatment will lead to continued medication adherence and beneficiary convenience.

Overall, UHG believes that there is strong support for CMS to modify its current mail-order auto-refill policy to ease the burden on Part D Sponsors, while at the same time improving medication adherence and increasing beneficiary access and convenience.

Other

Star Ratings: Remove Beneficiaries Who Decline Outreach from Health Risk Assessment Measure

The Health Risk Assessment (HRA) Measure - C08, compares the number of initial and annual HRAs performed to the total number of eligible enrollees. The measure includes beneficiaries who refuse or decline outreach in the total number of eligible enrollees. By including "refusals," MA Plans are penalized for respecting beneficiaries' desire not to be contacted. This negatively impacts the overall beneficiary experience.

Recommendation:
UHG recommends CMS align the Star Rating Measure C08 Technical Notes with the HRA Part C Reporting Requirements by removing beneficiaries who refuse to complete an HRA, or decline outreach, from the denominator.

Star Ratings: Osteoporosis Management in Women who had a Fracture

For the last several years one of our largest Medicare PCP groups has instituted a practice in their clinics to proactively suggest Bone Mineral Density (BMD) assessments to certain patients and subsequently screen patients at high risk for fracture (i.e., women over age 65). Depending on the patient visit intervals, the screening is completed every one or two years. Additionally, the provider group suggests BMD assessments in postmenopausal women less than 65 years of age if one or more risk factors are present (*see example A*).

Osteoporosis has no clinical manifestations until there is a fracture, thus identifying it before a fracture occurs via one of the screening methods can lead to early management and treatment of osteoporosis. Furthermore, preventing fractures could ultimately result in a decrease in morbidity/mortality, health care costs, and utilization, thus improving quality of life as a whole.

The NCQA Osteoporosis Management in Women Who Had a Fracture (OMW) measure specification currently only looks at women after they have had a fracture and requires a BMD screening or medication to treat osteoporosis within the six months after the fracture. Proactive screenings are not included in the measure specification. However, beneficiaries being excluded have a very real potential of decreasing the denominator so significantly that the measure becomes in jeopardy of falling below the 30 beneficiary threshold for inclusion in ratings. It seems counterintuitive that proactive screenings should effectively penalize a MA Plan.

Recommendation:
The clinical approach is the same proactively or retrospectively, accordingly, the measure specification should take both proactive and retroactive screenings into consideration. One option would be to allow proactive screenings to count toward numerator compliance or allow MA Plans to report the measure regardless of denominator threshold.

Regardless of the approach taken, MA Plans should not be penalized for taking a proactive approach.

Example A

Clinical risk factors for fracture

Advancing age
Previous fracture
Glucocorticoid therapy
Parental history of hip fracture
Low body weight
Current cigarette smoking
Excessive alcohol consumption
Rheumatoid arthritis
Secondary osteoporosis (eg, hypogonadism or premature menopause, malabsorption, chronic liver disease, inflammatory bowel disease)

Star Ratings: Cash Claims for Part D Medication Adherence Measures Medications

UHG is requesting CMS to consider alternate ways of accepting data for qualifying adherence

medications for diabetes, hypertension and/or cholesterol where beneficiaries may have filled prescriptions outside of the Part D benefit. Alternate data sources would allow CMS to have a holistic view of all the medications a beneficiary may be taking and a more accurate measure of their adherence. While it is preferred that beneficiaries always use their benefit at the pharmacy, there are times when they may be filling their medications outside of their benefit. As such, these claims are not being counted in the PDC calculation that is used to measure adherence. While there is no good way for Part D Sponsors to capture these types of claims, UHG is requesting CMS consider:

- Allowing pharmacies to submit cash claims as $0 claims so PDEs can be submitted and they can be used in the PDC calculation.
- Allowing Part D Sponsors to resubmit claims to generate $0 PDEs for claims that have been processed outside the Part D benefit.
- Allowing Part D Sponsors to submit supplemental data to CMS around these claims.

UHG is also supportive of other ideas CMS may have to ensure medication adherence is being calculated accurately for the beneficiaries.

Star Ratings: Updating the Drug List for Part D Clinical Star Measures More Frequently

UHG is requesting CMS to consider updating the drug lists for the three Part D medication adherence measures and the SUPD measure more frequently than twice a year. This will allow Acumen results to be more in line with actual performance during the year and allow Part D Sponsors to be able to track their performance more closely. An updated drug list will also have the added advantage of Part D Sponsors having an external list to compare their internal drug lists against.

Special Needs Plan (SNP) Care Management: Annual Assessments Part C Reporting Technical Specifications

UHG experienced a need for a greater level of detail within the Part C SNP Care Management technical specifications for SNP Care Management: Annual Assessments over the course of the past three years due to the high level nature at which the technical specifications are written. As such, we have submitted questions to the Part C Plan Reporting mailbox but have received inconsistent guidance from different mailbox responders. MA Plans would benefit from additional CMS clarification in the technical specifications to ensure greater consistency of year over year reporting and more accurate Star Ratings. Such clarification should reflect CMS responses to all MA Plan submitted questions. UHG respectfully requests notice in order to implement any technical specification changes by moving the applicable Star Rating measures to the Display Measure page. UHG also recommends that CMS develop FAQs similar to DMAO Mailbox FAQs to aid in consistent interpretation of the technical specifications.

The Extreme and Uncontrollable Circumstances Policy for the Merit-based Incentive Payment System (MIPS) in 2017 Transition Year

CMS issued an interim final rule with comment period (CMS-5522-IFC), published in the CY 2018 Quality Payment Program final rule with comment period, to address extreme and uncontrollable circumstances for the MIPS Advancing Care Information, Quality, and Improvement Activities performance categories

for the transition year of MIPS. This policy does not apply to the Cost performance category since it has a 0% weight in the transition year.

Under this policy, CMS has attempted to lessen the burden of clinicians located in Federal Emergency Management Agency (FEMA) designated areas affected by Hurricanes Harvey, Irma, Maria, or Nate or the California Wildfires by not requiring them to submit an application to reweight the performance categories.

UHG supports this MIPS hardship exemption for impacted counties affected by natural disasters.

Undeliverable Mail

UHG recommends that CMS evaluate current expectations that require MA Plans to continue to send their members' mail to addresses for which undeliverable notices have previously been received. UHG believes that this creates unnecessary privacy risks by sending mail to addresses where we have received confirmation that a beneficiary is no longer receiving mail. We also believe that it creates unnecessary administrative burden to MA Plans.

Recommendation:
UHG recommends a revision to the guidance to allow MA Plans to discontinue mailing after reasonable attempts have been made to contact a beneficiary once an undeliverable notice is received.

Complaint Tracking Module (CTM)

In UHG's experience, some CTMs assigned to the MA Plans are related to circumstances outside of MA Plans' control. As MA Plans work on their CTMs to remedy a beneficiary's or provider's concern, if the root cause issue is a function of another MA Plan or agency's actions, we may be unable to assist and resolve.

Recommendation:
UHG recommends that the CTM process be evaluated as it relates to the method by which MA Plans are assigned CTMs and held responsible for addressing the matter at hand.

UHG requests that CMS establish processes for MA Plans to collaborate with CMS in order to successfully address the matter, as well as revisit the assignment of CTMs when the MA Plan does not have a role to play in the resolution.