

January 16, 2018

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-5522-FC  
P.O. Box 8016  
Baltimore, MD 21244-8016

**RE: *Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Proposed Rule***

Dear Administrator Verma:

UnitedHealth Group (UHG) is pleased to respond to the Centers for Medicare and Medicaid Services' (CMS) request for comments regarding the Contract Year 2019 Policy and Technical Changes to the Medicare Advantage (MA), Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs (Part D), and the PACE Program Proposed Rule, as well as the Request for Information (RFI) on Manufacturer Rebates and Pharmacy Price Concessions at the Point of Sale.

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 270,000 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 27 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.

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 13 million people through more than 30,000 physicians, 1,100 primary, urgent and surgical care centers; and more than 1.2 million in-home health visits per year. In addition, OptumRx pharmacy care services uses the most frequent health care consumer touch point – the pharmacy – to provide distinctive whole-person care, turning a

traditionally disconnected, transactional experience into one that integrates the entire health care experience.

The CMS Proposed Rule presents an opportunity to build upon the successes of the MA and Part D programs. These public-private partnerships have proven the ability to improve quality and reduce costs that meet seniors' health care needs. For example, MA is delivering superior results to over 19 million beneficiaries today, including 37% who have fixed annual incomes at or below \$20,000. MA is meeting beneficiaries' health care needs in a coordinated manner and at a local level – and the outcomes are compelling. In fact, beneficiaries in MA return to the hospital 20% less often and are 20% more likely to receive annual preventive care as compared to beneficiaries in Medicare Fee-for-Service (FFS). The Part D program is a great example of how Pharmacy Benefit Managers (PBMs) are effectively delivering value to the health care system and consumers – saving the Federal government and seniors \$24 billion in 2015, and estimated to save \$900 billion from 2016-2025 according to a June 2017 study prepared by Oliver Wyman.

UHG appreciates and is supportive of several of CMS' proposed policies focused on improving health outcomes, reducing health care costs, and bringing predictability and stability to MA and Part D. Specifically, UHG applauds CMS's policy proposals to:

- Enable Value-based Insurance Design in MA by removing meaningful difference requirements and interpreting the uniformity of benefits requirements to allow plans to provide beneficiaries access to benefit designs that meet their individual needs and improve outcomes;
- Remove onerous administrative burden on data submissions for the Medical Loss Ratio;
- Allow Part D the flexibility for mid-year formulary change, which will enable plans to respond to ongoing clinical innovation and ensure consumer access to the most affordable option; and
- Bring predictability and stability to the CMS Star Rating System by requiring that all changes be announced during the annual Rate Setting process and that new measures are announced two years before they count towards a plan's overall Star Rating.

Additionally, UHG has several policy recommendations focused on bringing further stability and predictability to MA and Part D to maximize the value of these programs for both beneficiaries and taxpayers.

#### **Request for Information – Point of Sale Pharmacy Price Concessions and Point of Sale Rebates in the Part D Program**

##### *Point of Sale Pharmacy Price Concessions in the Part D Program*

UHG supports policies that lower drug spending, including premiums and drug costs, at the point of sale (POS), and that bring transparency to the health care system. We acknowledge that requiring plans to apply all direct pharmacy price concessions at the POS would (i) lower the costs of drugs at the POS for many beneficiaries, and (ii) improve drug cost transparency. Pharmacy price concessions at the POS would also result in modest premium increases across most Plan Sponsors. If CMS determines that applying pharmacy price concessions at the POS will strike the appropriate balance between premiums, POS costs and transparency, UHG would be prepared to implement the requirement.

##### *Point of Sale Rebates in the Part D Program*

In contrast, any new requirement that results in the application of pharmaceutical manufacturer rebates at the POS will: (i) significantly increase premiums, (ii) not improve drug cost transparency; (iii) deteriorate the structural integrity of the stand-alone Part D program by potentially exposing Part D

plans to longer-term adverse selection; and, (iv) decrease the amount of rebates offered. Accordingly, UHG would strongly oppose any change to the current administration of manufacturer rebates, including any requirement that Part D plans apply them at POS.

As a reminder, CMS' own estimate, detailed in the 2019 Proposed Rule, quantifies that applying a rebate at the POS could raise premiums by \$28 billion and government costs by \$82 billion over the next 10 years. CMS' proposal to implement POS rebates threatens a program that has demonstrated success across a variety of metrics, including:

- More than 85 percent of beneficiaries reporting overall satisfaction with the Part D program;
- Premium growth has averaged 2 percent annually from 2013-2017, and is decreasing by 3.5 percent in 2018; and
- Total program spending is \$556 billion less than anticipated over the first ten years of the program due to the performance of PBMs and Part D Plan Sponsors.

### **Implementation of Comprehensive Addiction and Recovery Act of 2016 (CARA) to Address Opioids**

UHG is supportive of CMS' intent to implement the CARA Act to curb the misuse of opioids by beneficiaries at-risk for prescription drug abuse. The Centers for Disease Control and Prevention (CDC) guidelines provide an important framework to effectively address inappropriate prescribing. However, key CMS regulatory barriers currently limit the ability of health plans to implement the CDC guidelines and curb inappropriate use of opioids. UHG believes that to address the misuse of prescription drugs CMS should strengthen prescribing practices; implement alternative pain management treatments; and increase access to Medication Assisted Treatment (MAT) in combination with psycho-social therapy. These solutions should all be informed by data to predict and prevent opioid misuse, identify individuals in need of treatment, and address inappropriate prescribing of opioids by providers. Specifically CMS should:

- Clarify that complaints about opioid policy enforcement and by patients who are misusing opioids will not lower a health plan's quality ratings;
- Specify that health plans may require providers to give written evidence that shows an opioid is medically necessary for the patient, and uphold decisions to deny coverage for an opioid when the evidence is insufficient;
- Allow health plans the flexibility to target patients at-risk of opioid misuse and implement a "lock-in", without delay or approval from a provider;
- Permit health plans greater flexibility to review a patient's medications, identify risks for opioid misuse, limit access to opioids in accordance with CDC guidelines; and
- Authorize health plans to evaluate individual patients to determine an appropriate opioid dose and offer non-opioid drug alternatives and offer non-opioid drug alternatives.

### **Any Willing Pharmacy**

UHG is opposed to the regulatory constraints that CMS is proposing related to Any Willing Pharmacy requirements, as well as the proposed definitions of "retail pharmacy" and "mail-order pharmacy." As a result of this proposal, Part D Plan Sponsors and their contracted PBM's would no longer have the authority to establish pharmacy networks, which promote quality and reduce costs, including through management of fraud, waste and abuse. This CMS proposal would serve to increase the cost of drugs for America's seniors, impacting beneficiary access to high-quality, affordable care and undermine a Part D plan Sponsor's obligation to achieve the lowest total cost for covered beneficiaries.

## **Seamless Enrollment**

CMS proposes to allow seamless enrollment for Dual-Eligibles to ensure these beneficiaries have access to a high-quality health care options. UHG recommends CMS also create auto enrollment between Low Income Subsidy (LIS) beneficiaries enrolled in Part D and a local Dual- Special Needs Plan. This would simplify the enrollment process for LIS beneficiaries to help vulnerable beneficiaries receive the maximum value of the Medicare benefit, including an out-of-pocket maximum, reduced cost sharing, and care coordination services that are available in MA.

Detailed below are UHG's technical comments on the 2019 Part C and Part D Proposed Rule, as well as the RFI. As always, UHG welcomes the opportunity for constructive discussion and collaboration as part of this comment process, and looks forward to sharing any additional data or information that supports Medicare beneficiaries, CMS, and American taxpayers. We are committed to providing Medicare beneficiaries with high-quality, value-based care and affordable health care options.

Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard J. Migliori", with a stylized flourish at the end.

Richard J. Migliori, M.D.  
Executive Vice President and Chief Medical Officer

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## Provisions of the Proposed Regulations Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability

### Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions

Overall, UHG supports the regulatory framework proposed by CMS that would allow Part D Sponsors the flexibility to limit at-risk beneficiaries' access to frequently abused drugs to a specific prescriber(s), a specific pharmacy, or both, and has the following comments on the proposed framework.

#### *Integration of CARA and Current Part D Opioid DUR Policy and OMS*

UHG supports the integration of a pharmacy/prescriber lock-in with the current Drug Utilization Review (DUR) policy and the Overutilization Monitoring System (OMS). Given the system modifications and/or enhancements that Part D Sponsors will likely have to make to integrate the lock-in policies, as well as any implementation guidance, UHG encourages CMS, in the Final Rule, to continue to allow Part D Sponsors the option to adopt a phased-in approach to the lock-in programs, rather than placing any requirement on Part D Sponsors that the programs be fully integrated and launched by the January 1, 2019 CARA effective date. UHG also encourages CMS to 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.

#### *Definition of "Frequently Abused Drug"*

UHG supports CMS' proposal that the initial focus of the program in 2019 should be on prescription opioids. UHG believes, however, that the definition of "Frequently Abused Drug" as proposed, would limit Part D Sponsors' ability to expand their lock-in programs in the future to include other drugs that in the experience of the Part D Sponsor are frequently abused. Therefore, UHG encourages CMS to revise the definition of "Frequently Abused Drug" to allow for a process that would give Part D Sponsors, not just CMS, the ability to expand the scope of drugs included in lock-in programs based on Part D Sponsor experience and subject to CMS' approval.

#### *Requirements for Limiting Access to Coverage for Frequently Abused Drugs*

UHG supports CMS' proposal to permit a Part D Sponsor to implement the lock-in to protect the health of the beneficiary and the Part D benefit if a prescriber fails to respond to a Part D Sponsor's lock-in request and the Part D Sponsor has supporting data showing the enrollee is engaged in overutilization behavior. However, it is imperative that Part D Sponsors have the flexibility to implement a pharmacy/prescriber lock-in regardless of whether the prescriber agrees. Based on UHG's experience with the existing DUR program, a beneficiary level edit is not enough to manage a beneficiary's opioid utilization, as edits are overturned or modified through the coverage determination process by prescribers who did not initially request the edit. Similarly, if a pharmacy/prescriber does not agree to the Part D Sponsor's lock-in request, the beneficiary will continue to have access to multiple pharmacies/prescribers, and Part D Sponsors will be unable to protect the health of the "at risk beneficiary" from a clinical perspective or address the beneficiary's ability to obtain prescriptions by shopping pharmacies/prescribers.

Accordingly, UHG recommends that CMS not mandate that Part D Sponsors obtain prescriber agreement before implementing lock-in. This will preserve Part D Sponsors' ability to protect the integrity of the program by preventing fraud, waste and abuse (FWA).

#### *Special Election Period*

UHG understands and agrees with the need to better manage opioid utilization and improve care coordination in full-benefit dually eligible and other low-income subsidy (LIS) beneficiaries who have been identified as "**at-risk**" by limiting the availability of the special election period (SEP) typically allowed for these beneficiaries. UHG notes that while it agrees with the proposal to implement the SEP provision, this change will likely lead to increased beneficiary confusion, dissatisfaction, complaints to Medicare (CTMs), grievances, etc. UHG also notes that beneficiaries may be unaware that they have exhausted their single SEP opportunity and will "enroll" with a new plan, only to learn that after enrolling, that they are ineligible for a SEP due to the lock-in status. UHG encourages CMS to take these factors into account when evaluating beneficiary complaints and plan performance, as well as excluding identified "at risk beneficiaries" with a restriction (beneficiary-level edit and/or lock-in) and beneficiaries' complaints about opioids from beneficiary Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys and CTM numbers for Stars purposes.

#### *Integration of CARA and Current Part D Opioid DUR Policy and OMS*

UHG requests clarification on how Part D Sponsors should handle current drug edits, such as the formulary-level cumulative morphine equivalent dose (cMED) safety alert within the scope of the current DUR policy and implementation of the lock-in drug management program. For example, CMS should clarify that an approved authorization for cMED above the Part D Sponsor's threshold will not negate identification/inclusion for case management. In addition, UHG asks CMS to clarify that the beneficiary-level edit(s) and lock-in provisions will take precedence over the cMED approved authorizations.

UHG continues to encourage CMS to request that the Pharmacy Quality Alliance (PQA) update the opioid measure threshold to 90 mg morphine milligram equivalents (MME) in order to align with the Centers for Disease Control (CDC) guidelines, and the revised OMS criteria. As CMS may be aware, Part D Sponsors are currently measured against the Patient Safety Outlier measures, which are more lenient than the CDC guidelines and are based on the number of beneficiaries who use more than 120 mg morphine equivalent dose (MED) of opioids for 90 days or longer, regardless of the number of providers and pharmacies. They also measure contract performance by utilizing a different cumulative MME value than what is recommended by the CDC and the 2018 OMS guideline. By requesting that the PQA update the opioid measure threshold, CMS will not only help ensure alignment with CDC guidelines, and the revised OMS criteria, but it will also enable Part D Sponsors to work toward improving their performance against the same criteria.

#### *Definition of Clinical Guidelines and Program Size*

UHG supports use of the OMS criteria as the clinical guidelines for plan year 2018, but recommends that CMS give Part D Sponsors the flexibility to adjust clinical guidelines if the OMS guidelines do not target the Part D Sponsors' most at risk utilizers (i.e., high dose utilization regardless of the number of prescribers). As previously emphasized, Part D Sponsors must have flexibility to establish and modify clinical guidelines based on their patient population and utilization patterns, as well as to apply the



criteria more frequently (i.e., monthly evaluation). If CMS has concerns with the changes made by Part D Sponsors to the employed clinical guidelines, UHG recommends that CMS establish a process that would allow Part D Sponsors the opportunity to submit guideline changes and the reason for changes to CMS (similar to the cMED safety edit changes that are submitted to CMS through HPMS). This will allow Part D Sponsors flexibility, while at the same time giving CMS insight and continued visibility to the guidelines being employed by the Part D Sponsors.

UHG agrees that prescriber grouping may minimize unnecessary outreach to prescribers within the same practice; however, UHG asks CMS to give Part D Sponsors flexibility with adopting prescriber grouping based on existing resources. UHG has concerns with CMS' proposed methodology for grouping providers based on a single Tax Identification Number (TIN). Since a provider's National Provider Identifier ("NPI") may be associated or tied to one or more TINs, and a TIN is not included on pharmacy claims, Part D Sponsors will be unable to determine if multiple prescribers are associated with the same single TIN and should therefore be counted as a single prescriber. It is also worth noting that if prescriber grouping is based on multiple providers sharing at least one TIN, regardless of other TINs the provider may be affiliated with, then fewer beneficiaries will be identified based on the total provider count. Therefore, UHG recommends that CMS instead group providers based on prescribers who share a single NPI, not a single TIN. UHG is also concerned about treating pharmacies with multiple locations as one pharmacy under the clinical guidelines. UHG urges CMS to take into consideration the fact that Part D Sponsors are not able to determine if a pharmacy with multiple locations utilizes the same real-time electronic data. UHG also asks CMS to clarify if the pharmacy grouping is only for the guideline identification process, or if CMS also intends to apply the pharmacy grouping when a pharmacy lock-in is implemented.

#### *Exempted Beneficiaries*

UHG recommends that in addition to hospice and cancer, CMS exempt beneficiaries receiving palliative and end of life care from the lock-in programs. To the extent CMS agrees with UHG's recommendation, UHG requests that CMS either provide Part D Sponsors with the information on which beneficiaries are receiving palliative and end of life care, or allow Part D Sponsors to determine this information through case management.

In addition, UHG understands that beneficiaries in long term care (LTC) facilities should be exempt from the drug management program because of the use of a single pharmacy. However, UHG requests CMS' guidance on how the lock-in provision/beneficiary-level edit should be applied for a beneficiary who may move in and out of an LTC (i.e., a beneficiary is identified as at-risk and is managed via a pharmacy lock-in before entering a LTC facility). The Long-Term Institutionalized (LTI) Resident Report is released to Part D Sponsors quarterly, and there may be differences between the LTI Resident Report and the Part D Sponsor's current Part D enrollment; therefore, CMS should issue guidance on which sources to utilize to identify a beneficiary's current LTC status.

#### *Case Management*

CMS proposes that the case management programs require **all beneficiaries reported by OMS** to be reviewed by Part D Sponsors. UHG generally supports CMS' proposal since the 2018 OMS guidelines will apply a rolling six (6) month look-back versus a 12 month look-back, and UHG expects there to be less disparity between beneficiaries identified internally and OMS identified beneficiaries, with the exception of newly enrolled beneficiaries from another plan (i.e., beneficiaries with multiple prescription drug

event (PDE) data). However, UHG recommends that CMS clarify in the Final Rule that “all beneficiaries reported by OMS” means those beneficiaries who are current utilizers under the Part D Sponsor and not any non-matched outliers who are identified as having multiple PDE data flags. If CMS expects Part D Sponsors to conduct case management on non-matched outliers, then the outlier response due date should be extended (i.e., to next OMS quarter), as Part D Sponsors may need to contact the prior contract for case details and conduct case management using multiple PDE data. In extending the outlier response due date, CMS should consider that the volume of non-matched outliers may differ based on the size of the Part D Sponsor.

### *Beneficiary Notices*

UHG supports CMS’ proposal to notify beneficiaries that a change to their existing benefit will take place. However, UHG respectfully requests that CMS reevaluate its proposed beneficiary notices to support the lock-in program. UHG has concerns that the number of notices that CMS is proposing to be implemented for the lock-in program will lead to beneficiary confusion and will prompt grievances and CTMs. In addition, UHG anticipates that it will lead to administrative burden and potentially a delay in the implementation of the lock-in and/or lock-in plus beneficiary-level edit. UHG proposes an alternate process for CMS’ consideration:

***Beneficiary-level edit only based on the existing DUR policy:*** Continue with existing notification process.

***Pharmacy lock-in +/- Beneficiary –level edit :*** After case management is complete (provider outreach), the beneficiary receives a single notice, which includes the beneficiary-level/lock-in description, implementation/effective date (45 days from the initial notice to account for a 30 day response period and 14 days for the Part D Sponsor to implement the edit after beneficiary confirmation/preferences are received), available network pharmacy alternatives for lock-in (based on the two (2) most recent utilized pharmacies) and an option to choose a different pharmacy not already listed, but in the network. The notice will include a request that the beneficiary submit a response within 30 days (written or telephonically). The notice will also include the actions that the Part D Sponsor will take if no response is received from the beneficiary within the allotted timeframe, including that if no response is received from the beneficiary, the Part D Sponsor will be allowed to proceed with implementing the edit/lock-in noting that the first pharmacy listed as a network pharmacy will serve as the lock-in pharmacy for the beneficiary. The notice will also indicate whether the edit/lock-in is implemented with prescriber consensus (name of prescriber included) and whether the Part D Sponsor implemented the edit due to no provider response.

CMS could also consider including the following information in the single notice:

- The reason why the beneficiary has been determined to be “at risk”;
- A solicitation for the beneficiary’s preferred prescriber and/or pharmacy;
- The effective date of the edit;
- An explanation of what will happen if the beneficiary does not select a preferred pharmacy/prescriber;
- Who the beneficiary can contact for questions regarding the notice; and
- How the beneficiary can request changes to the provider/pharmacy included in the lock in.

UHG respectfully disagrees with CMS' proposal that Part D Sponsors send a beneficiary a second notice 30 days after the initial notice when the current DUR policy only requires that beneficiaries receive a single notice. If CMS finalizes its proposal requiring a second notice, UHG urges CMS to take into account the need to minimize beneficiary confusion and frustration and make the second notice simple and direct. To that end, UHG recommends that CMS allow Part D Sponsors the opportunity to review and comment on any proposed letters and that at a minimum, the second notice only serve to confirm the outcome of the at-risk identification (i.e., selections) by including the following information:

- A reference to the first notice;
- The effective date of the edit/lock in;
- The prescriber/pharmacy lock-in;
- Who the enrollee can contact for questions regarding the notice; and
- How the enrollee can appeal the lock-in.

UHG also recommends that CMS revise its process on providing notification to beneficiaries who undergo a plan change offered by the same Part D Sponsor. If CMS does not modify the current process, beneficiaries who move to a new contract within the same parent organization will receive an additional notification explaining that the current restriction/lock-in will continue under the new contract. This additional notification should not be required, as it will only lead to beneficiary confusion.

Finally, UHG disagrees with the proposal to provide an alternate second notice to a potential at-risk beneficiary if, after providing the initial notice, the Part D Sponsor determines that the potential at-risk beneficiary is not an at-risk beneficiary. UHG does not believe there is any utility in an alternate second notice, as a Part D Sponsor should only contact a beneficiary after the "at risk status" is confirmed through case management during provider engagement.

#### *Special Requirement to Limit Access to Coverage of Frequently Abused Drugs to Selected Prescribers*

As previously noted in our comments, UHG recommends that the prescriber limitation/lock-in provision retain flexibility to allow Part D Sponsors to determine when a prescriber lock-in is appropriate and necessary. UHG encourages CMS to not limit a prescriber lock-in to a six (6) month waiting period (identification in OMS reporting). UHG could foresee a situation where beneficiaries continue to identify after implementation of a pharmacy lock-in and a beneficiary-level edit, and multiple prescribers overturn the implemented beneficiary-level edit through the exception process. In that scenario, the Part D Sponsor should have the flexibility to implement a prescriber lock-in to manage utilization and coordinate care without delay. If CMS does not afford Part D Sponsors the flexibility to implement lock-ins when appropriate based on identified beneficiaries and case management, then CMS should not consider beneficiaries enrolled in a contract that has been identified as an outlier based on Patient Safety measures to be an outlier. Similarly, contracts within a Part D Sponsor's parent organization should not be identified as outliers, if identified overutilization cannot be managed. While only 1 of 3 patient safety measures involving opioid usage (Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D)) is considered a Star Display Measure at this time, UHG recommends that CMS not move this to a Star Measure, particularly if Part D Sponsors do not have the needed flexibility to manage edits appropriately, as Part D Sponsors should not be penalized if they are not able to effectively address the issue.

### *Selection of Pharmacies and Prescribers/Beneficiary Preference*

UHG supports CMS' proposal for utilizing **network** pharmacies and/or prescribers for at risk beneficiaries. For PDP only beneficiaries, the Part D Sponsor will work with the beneficiary to select a prescriber that the beneficiary prefers, unless an exception applies.

However, UHG opposes CMS' proposal to allow beneficiaries to submit preferences "at any time". Allowing a beneficiary to change preferences at any time creates the potential for abuse and may place significant administrative burden on the Part D Sponsor if it has to obtain confirmation from prescribers and/or pharmacies multiples times per month for any beneficiaries who want a change in preference. UHG recommends that CMS limit the number of times a beneficiary can submit their preferences to three (3) times per plan year, and that it only be allowed under limited circumstances such as a residence change.

### *Reasonable Access*

As previously noted in the comments, Part D Sponsors do not currently have the capability to determine whether a pharmacy shares real time data (i.e., pharmacies owned by the same parent company, but different systems). Therefore, UHG recommends that CMS not limit Part D Sponsors from locking in beneficiaries to one pharmacy location for pharmacies that have multiple locations only when the pharmacies share real-time data, unless CMS provides Part D Sponsors with the information on which pharmacies share real-time electronic data.

### *Drug Management Program Appeals*

UHG understands that the implementation of a beneficiary-specific point of sale (POS) claim edit or a limitation on the at-risk beneficiary's coverage for frequently abused drugs to a selected pharmacy(ies) or prescriber(s) would be an at-risk determination (a type of initial determination that would confer appeal rights)", such that any dispute initiated by a beneficiary would be treated as a redetermination/appeal. However, as CMS also indicates, a beneficiary "always retains the right to request a coverage determination under existing § 423.566 for any Part D drug that the beneficiary believes may be covered by their plan," and also believes "that appeals of an at-risk determination made under proposed § 423.153(f) should involve consideration of all relevant elements of that at-risk determination." Under CMS' new proposal, UHG seeks clarification as to how to handle a dispute involving the quantity limit on a beneficiary-specific POS claim edit and a dispute about a pharmacy/prescriber selection; is it CMS' expectation that a Part D sponsor would handle both requests under the same appeal (as opposed to a coverage determination for the quantity limit and an appeal for the pharmacy/prescriber selection)?

UHG believes that it is appropriate for beneficiaries to have an opportunity to appeal, but recommends that appeal rights should be limited to the beneficiary-level edit, the selected pharmacy or the prescriber, and not the underlying criteria for identification and guidance. In addition, CMS should also confirm that beneficiaries will not be allowed to continue to receive inappropriate fills during the appeals process.

UHG requests additional clarification as to whether a Part D Sponsor must obtain confirmation from the beneficiary's new prescriber/pharmacy selection within the appeals timeframes (72 hours for expedited and 7 days for standard requests) if a beneficiary appeals the Part D Sponsor's initial selection of a

prescriber or pharmacy. If so, UHG has concerns with obtaining prescriber/pharmacy confirmation within such a short window. Additionally, UHG requests CMS provide Part D Sponsors with guidance that specifies the criteria to utilize for pharmacy/prescriber lock-in and opioid restriction appeal reviews (e.g., is a prescriber's attestation sufficient?).

#### *Termination of Identification as an At-Risk Beneficiary*

CMS proposes that the identification of an at-risk beneficiary must terminate at the earlier of the date the beneficiary demonstrates that he/she is no longer likely to be an at-risk beneficiary or the end of a 12-calendar month period calculated from the effective date of the limitation. Although a 12-month lock-in period is common in Medicaid lock-in programs, UHG has concerns with removing restrictions based on an arbitrary period of time particularly when the current DUR policy does not require it. UHG recommends that CMS require a beneficiary remain identified as an at-risk beneficiary until the provider managing the beneficiary's care requests removal. This approach is consistent with the current DUR policy and will ensure that beneficiary-level edits remain implemented as long as necessary, as opposed to a finite period of time. In addition, UHG notes that an arbitrary termination is unnecessary when, as is the case here, the prescriber/pharmacy lock-in and beneficiary-level edit can be terminated at any time at the discretion of the prescriber in the event that new information becomes available.

#### *Data Disclosure and Sharing of Information for Subsequent Sponsor Enrollments*

UHG supports the integrated reporting process for both OMS and CARA, but recommends CMS consider the following changes to the overall process:

1. Include specific edits that differentiate between a beneficiary-level edit, prescriber/pharmacy lock in, combination edit and lock-in for each plan;
2. Add a Part D Sponsor summary page that displays all active edits and lock-ins;
3. MARx system enhancements to recognize internal and external contract changes (the information contained in MARx is at the contract level and not the level of the parent organization, therefore, when a beneficiary changes contracts internally within the same parent organization, Part D Sponsors are required to re-notify the beneficiary which leads to confusion and burden); and
4. Make changes to the MARx system to allow more complete case data to be shared between Part D Sponsors without the need for Part D Sponsors to exchange emails. This would allow for timely data sharing at the time the Part D Sponsor receives notification that a beneficiary with an edit has enrolled in the Part D Sponsor's plan. The case data should include type of edit, whether the edit was implemented administratively by the Part D Sponsor, or with provider consensus, applicable prescriber information who requested the edit, and subsequent edit modifications due to coverage exceptions/appeals (i.e., PS1 edit code to a PS2 edit code).

#### **Flexibility in the Medicare Advantage Uniformity Requirements**

To date, CMS has required Medicare Advantage (MA) Plans to provide all enrollees in a MA Plan access to the same benefits at the same level of cost sharing. We support CMS' 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. We request that CMS allow MA Plans the ability to communicate information on these tailored benefits to all enrollees, 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.

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. For example, an MA Plan may authorize transportation on a MA Plan without a transportation benefit for particular beneficiaries who have a serious chronic condition, 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.

In addition to reconsidering the historical interpretation of the uniformity requirements, we ask that CMS also consider reviewing the interpretation of the uniform premium requirements to allow reduced premiums for beneficiaries who sign up for automated premium payments. All beneficiaries would be treated equally because it would be made available to all beneficiaries. In addition, automated payments reduces unnecessary mail, reduces the number of beneficiaries who simply forget to pay premiums (and therefore potentially face disenrollment), and simplifies MA Plan administration. Allowing a nominal discount when beneficiaries choose a streamlined payment option will not create significant differences in premiums between beneficiaries who choose that option and those who do not, but will benefit all beneficiaries because an increase in automated programs helps keep premiums and benefits stable for all beneficiaries.

### **Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 422.100 and 422.101)**

UHG has no comment on CMS' maximum out of pocket limit (MOOP) proposed changes, as it applies to individual MA Plans, but finds CMS' approach for EGWPs unduly limits groups from providing their desired retiree coverage through MA Employer Group Waiver Plans (EGWPs).

Many employer groups who purchase EGWPs seek to mirror the benefits for their retirees that they enjoyed as active employees. One common benefit design MA EGWPs choose is to use coinsurance to determine a beneficiary's share of the cost of a covered service.

CMS currently sets service category cost sharing limits on MA Plans (including EGWPs) in addition to a global, annual beneficiary MOOP. Complying with both the global, annual beneficiary MOOP and the service category limits complicates certain claim adjudications and can cause the EGWP to deviate from the employer's benefit intentions. For example, an employer intending for retiree plan beneficiaries to pay 10% of the MA Plan allowable amount for inpatient hospital visits, up to an annual beneficiary MOOP of \$3,500, is required to cap a beneficiary's share of the cost at \$1,801 for a 6-day inpatient stay. This causes undue beneficiary confusion and frustration for some EGWP beneficiaries in attempting to understand their MA Plan benefits, as they deviate from the benefits they had as active employees. Accordingly, UHG requests that CMS allow MA EGWPs to establish coinsurance amounts that exceed the annual fixed limits CMS establishes through the annual Rate Notice and Call Letter process provided that the EGWP actuarial equivalence standards are met and the modification does not deny or discourage access to covered medically-necessary health care items and services. This would allow the EGWP to better deliver an employer's intended benefits and increase simplicity and MA Plan understandability for MA Plan beneficiaries.

In addition, UHG has concerns with the manner and timing of the changes to cost share and MOOP limits as they apply to EGWPs. By the time the Final Rate Notice and Call Letter are released each year, almost 50% of our employer group plans for the following year have been quoted. Requiring plans to change benefits after quoting can be disruptive. Historically, these changes have been minimal, but large changes would be problematic. We ask that CMS provide more advance notice of any mandated MOOP and cost share changes for the upcoming year, or waive the applicability of these amounts for EGWPs as described above.

#### **Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§422.254 and 422.256)**

UHG supports CMS' proposal to eliminate the meaningful difference requirements for MA bid submissions starting with contract year 2019. We believe that Medicare beneficiaries will remain protected from discriminatory MA Plan benefit packages and will still have meaningful MA Plans to evaluate, as they make their annual elections.

#### **Coordination of Enrollment and Disenrollment Through MA Plans and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68)**

Section 1851(c)(3)(A)(ii) of the Social Security Act allows CMS to establish a process for individuals enrolled in a non-MA health plan offered by an MA organization at the time of his or her initial Medicare coverage election period to be deemed to have elected an MA Plan offered by the MA organization if he or she does not elect to receive Medicare coverage in another way. CMS proposes to limit the ability of MA Plans to use seamless enrollment to enrollment into DSNPs subject to five additional conditions. UHG objects to CMS limiting seamless enrollment to DSNPs and instead urges CMS to continue to allow MA Plans the current flexibility to submit seamless enrollment proposals for all lines of business. UHG appreciates CMS' concern that obtaining a beneficiary's Health Insurance Claim Number has proven difficult in the past; however, plans may develop methods that would solve this current problem and limiting seamless enrollment to DSNPs would prevent MA Plans from taking advantage of potential future opportunities to assist beneficiaries with obtaining MA coverage. If CMS retains the existing flexibility, UHG recommends that requiring state approval be limited to Medicaid to DSNP seamless enrollment and not be required for other types of seamless enrollment proposals. UHG also recommends reducing the initial beneficiary notification timeframe from 90 days to 60 days. UHG

believes that 60 days is sufficient time for the future Medicare beneficiary to consider whether he or she wants to opt-out of the seamless enrollment election. Finally, UHG recommends CMS also create auto-enrollment between LIS beneficiaries enrolled in a Part D Sponsor's plan and a local DSNP. This would simplify the enrollment process for LIS beneficiaries to help vulnerable beneficiaries receive the maximum value of the Medicare benefit, including an out of pocket maximum, reduced cost sharing and care coordination services that are available in MA.

### **Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (§ 422.60(g))**

UHG applauds CMS on its continued commitment to align dual eligible beneficiaries within the same organization for their Medicare and Medicaid benefits, as demonstrated throughout the proposed rule. Such alignment allows for a more holistic view of an individual, enabling whole-person care and reducing the system fragmentation that dual eligible beneficiaries often experience. Passive enrollment is one tool that can facilitate this alignment; numerous state Medicaid programs already leverage this approach by auto-assigning individuals to the Medicaid managed care organization that also administers the individual's Medicare (DSNP) benefits.

We support passive enrollment strategies that accomplish this alignment while protecting the interests and needs of the individual. Specifically, we agree with CMS that passive enrollment should be limited to full-benefit dual eligible beneficiaries and that a robust opt-out and special election period (SEP) will be required to preserve Medicare beneficiary choice. We also agree that this approach requires collaboration with each state and should be to the discretion of the state to allow, for example, through a MIPPA contract modification. This approach would ensure that an organization's Medicaid performance can be considered in addition to the Medicare quality performance CMS is proposing.

We encourage CMS to consider expanding its proposed use of passive enrollment beyond those individuals whose existing integrated DSNP is interrupted. For example, as states implement Medicaid managed care or managed long-term services and supports (MLTSS) programs, or as they "carve-in" dual eligible beneficiaries to existing Medicaid managed care programs, it would be beneficial to allow states to leverage passive Medicare enrollment mechanisms that facilitate Medicaid—Medicare integration for individuals enrolled in Fee-for-Service Medicare. We also encourage CMS to allow states the flexibility to determine through their MIPPA agreements which DSNPs are eligible to participate in passive enrollment, rather than limiting it to fully integrated dual eligible and highly integrated DSNP products defined by regulation.

### **Part D Tiering Exceptions (§§ 423.560, 423.578(a) and (c))**

UHG has concerns with CMS' proposals related to Part D tiering exceptions and urges CMS to reconsider its position 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. Currently, CMS allows Part D Sponsors to deny tiering exception requests for any drug that is on the Part D Sponsor's specialty tier. UHG supports this regulation. However, CMS also indicates that while Part D Sponsors are not required to allow tiering exceptions for drugs on the specialty tier to a more preferable cost-sharing tier, the specialty tier is not exempt from being considered a preferred tier for purposes of tiering exceptions. Not all beneficiaries have Part D Sponsors' plans where the cost share is a coinsurance, as opposed to a flat co-pay. 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. 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, the determination of 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 CMS' additional guidance 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 making the oral antipsychotic ineligible for reduction to the tier of the injectable antipsychotics.

### **Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (§423.38)**

Currently, full-benefit dual eligible beneficiaries have a Special Election Period (SEP) that allows them to change DSNPs every month. CMS is proposing to limit the ability to use a SEP at any time of the year to once per calendar year. UHG agrees that frequent movement between DSNPs can disrupt continuity of care for dually eligible individuals and interfere with care coordination and management. However, UHG cautions that the proposed approach of reducing dual eligible use of the SEP to a single opportunity may cause unintended confusion and frustration for beneficiaries. While CMS has proposed modifying beneficiary educational materials to accompany this change, UHG worries that dual eligible beneficiaries will be unaware when they have exhausted their single SEP opportunity and "enroll" with a new DSNP only to learn that after enrolling, they are ineligible for a SEP.

Accordingly, UHG recommends CMS consider delaying the implementation of this policy for at least a year and use the additional time to analyze current SEP utilization in more detail. For example, CMS might investigate questions such as: are those individuals who use a SEP multiple times per year moving from non-integrated to integrated DSNPs; are particular DSNPs or geographies more vulnerable to this beneficiary movement (disenrollment or enrollment); are individuals transitioning within the same parent organization multiple times per year; are there strategies to ensure beneficiaries will not attempt to use multiple SEPs after the new SEP policy is implemented; etc. These questions could inform the development of a SEP strategy that better encourages Medicare-Medicaid alignment, protects continuity of care and care coordination, and mitigates the unintended consequences of beneficiary confusion and frustration. CMS also might use this time to develop a strategy to inform DSNPs when an individual has exhausted his or her SEP for the year.

## Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

### *Background*

CMS requests comments on how well the existing Stars measures create meaningful quality improvement incentives. UHG believes CMS should adjust the Star measurement system to reward MA Plans that are achieving near perfect performance, rather than penalize them. For example, UHG recommends that those contracts that receive a 5 Star Rating on the Part D Appeals Timeliness measure and do not qualify for the Part D Appeals Upheld measure because they received less than 10 appeals, should automatically receive a 5 Star Rating on the Part D Appeals Upheld measure.

### *Contract Ratings*

UHG found a potential error on page FR 56380 of the Federal Register, which reads “For SNP specific measures collected at the PBP level, we propose that the contract level score would be an enrollment-weighted mean of the PBP scores using enrollment in each PBP as reported as part of the measure specification, which is consistent with current practice.” UHG understands that current practice weights the plan benefit package (PBP) scores by eligible population rather than PBP enrollment.

CMS proposes to continue to calculate the overall and summary Star Ratings at the contract level and solicited comments regarding alternate reporting at different levels. UHG supports the current practice of calculating the Star Ratings at the contract level. UHG has found that calculating the Star Ratings this way is a reasonable compromise between rating granularity, sample size feasibility, and administrative burden to MA Plans and providers. Reporting Star Ratings below the contract level (split by MA Plan or geography) would increase the administrative burden on providers/MA Plans and would leave many MA Plans unrated due to a lack of sufficient data to calculate a Star Rating. Reporting Star Ratings above the contract level (e.g., parent organization level) would reduce administrative burden, but would disadvantage large organizations. The rates of small organizations with small denominators would, by sheer chance, scatter across the industry distribution, while large organizations would receive rates that are accurate representations of their performance. The threshold clustering process would likely set the five-star threshold at the level reached by a cluster of highly-rated small outliers; parent organizations hoping to reach 5 stars would need to reach a level nearly impossible to reach except by extraordinary luck.

### *Contract Consolidations*

CMS proposes to modify the current practice of using the surviving contract rating when contracts are consolidated and replace it with an enrollment weighted mean of the measure scores of the surviving and consumed contracts. UHG recommends that CMS not implement this approach until two years following the announcement of the change in the Call Letter, which would mean announcing the change in the 2019 Plan Year Call Letter for implementation for the 2021 Plan Year. UHG strongly recommends that CMS delay implementing this change because plans have likely already started planning for the 2019 Plan Year and consolidation of contracts may be part of that strategy. CMS should provide additional time for MA Plans to develop and adjust any current strategy to account for the proposed change.

### *Adding, Updating, and Removing Measures*

CMS proposes to establish new measures and substantive updates to existing measures through future rulemaking, but indicates that prior to such rulemaking, CMS would announce them and solicit feedback in the Draft Call Letter. CMS will also place new measures on the Display Page for at least two years. UHG strongly supports CMS' proposed process because it will allow the industry to better execute on any changes and reduce costs because MA Plans will have the opportunity to more efficiently implement necessary operational changes.

In further support of this proposal, UHG offers a potential definition of "substantive change". UHG recommends using the CMS improvement score standard error formulas to determine if there has been substantive change. Measure data calculated under old methodology would be compared with the same year of data re-calculated under the new measure methodology so that methodology changes could be assessed in isolation. The rule could be that if more than 20% of contracts have significant improvement (or decline depending on the direction of the methodology change), the measure change would be defined as "substantive". Using the improvement score standard error formulas works for most measures, but not as well for the sample-based measures as those measures require more change to be considered mathematically significant. In the cases of those measures (i.e., Healthcare Effectiveness Data and Information Set (HEDIS) hybrid, Health Outcomes Survey (HOS), CAHPS), the difference that would be considered statistically significant should be reduced by half of the CMS-calculated standard error. This will help to account for changes that may not be mathematically significant, but are practically significant as they cross Star Rating thresholds.

### *Measure Set for Performance Periods Beginning on or After January 1, 2019*

CMS proposes that the following measures will be collected for the performance period beginning on or after January 1, 2019. UHG has the following recommendations.

#### *Rheumatoid Arthritis, Statin Use and the Health Outcomes Survey*

UHG believes the following specific HEDIS and HOS measures should be excluded or modified for patients with Advanced Illness: Rheumatoid Arthritis, Statin Use and the Health Outcomes Survey. Many challenges exist in treating and screening certain health conditions for patients with "Advanced Illness". Last year, in our response to the 2018 Draft Call Letter, UHG suggested all permanent nursing home residents should be considered as having "Advanced Illness", as they are commonly nearing the end of life or have severe chronic disease or functional limitations and many have elected comfort rather than longevity as the goal of their care.

#### *Breast Cancer Screening*

UHG believes that all permanently institutionalized beneficiaries, including those under age 65, should be excluded from the Breast Cancer screening measure. The top reasons for inability to screen in the under age 65 and disabled nursing home population arises from the inability to position beneficiaries for the procedure resulting from circumstances such as: functional quadriplegia, morbid obesity, immobility due to end stage multiple sclerosis, spastic hemiplegia, severe contractures, and severe brain damage. In addition, the family or beneficiary's goal of care is comfort, but they have not elected hospice, and such screenings are not necessarily appropriate.

As a secondary option, in contrast to a mammogram, there is a less invasive option to screen for breast cancer - an Automated Breast Ultrasound (ABUS). While not the gold standard for breast cancer screenings, it has been shown to be effective in identifying early and potentially aggressive breast cancers in select populations (e.g., those with dense breast tissue). Allowing for this screening option in long-term nursing home patients under age 65 would increase screenings for those unable to undergo mammography due to physical limitation or inability to cooperate. ABUS can be done with little or no discomfort to the beneficiary, as the position for imaging is lying flat in bed, takes only five minutes to perform at the bedside in the nursing home, and can be performed by trained non-licensed staff. UHG believes ABUS should be an acceptable method of screening for institutionalized patients under age 65 who are unable to undergo mammography.

#### *Osteoporosis Management Post Fracture and Controlling Blood Pressure*

UHG recommends exclusion of advanced illness permanent nursing home residents from the Statin Therapy for Patients with Cardiovascular Disease (SPC), Statin Use in Persons with Diabetes (SUPD) and Rheumatoid Arthritis Management (ART) measures.

Many permanently institutionalized MA beneficiaries/Institutional Special Needs Plan beneficiaries with Rheumatoid Arthritis have significant functional limitations, slowed gait speed, tolerate medications poorly, may commonly choose non-pharmacological interventions over pharmacological, have multiple comorbidities and an extremely high risk of infection. Their tolerance for Disease Modifying Anti-Rheumatic Drugs (DMARDs) is limited along with a much higher rate of serious adverse medication effects, particularly serious infections. Many beneficiaries permanently living in a nursing home with rheumatoid arthritis do not have symptoms linked to this condition. Thus, the risks of anti-rheumatic therapy for this population outweigh the benefits.

Similarly to ART, beneficiaries with limited prognosis such as permanently institutionalized beneficiaries frequently have risks of taking medications that outweigh benefits particularly when benefits take years to accrue. Many of these patients have been on statins that are now being discontinued in attempts to reduce polypharmacy as they have transitioned permanently into the nursing home setting. Others have had difficulty tolerating statin therapy. There is evidence that quality of life is improved with discontinuation of statin use in the setting of limited prognosis patients,<sup>1</sup> and it is considered safe and prudent to discontinue statins in patients taking them for primary prevention (SUPD) if prognosis is less than two years<sup>2</sup>.

#### *Improvement Measures*

CMS proposed a special rule to hold harmless sponsoring organizations that have 5 Star Ratings for both years on a measure used for the improvement measure calculation. For any identified improvement measure for which a contract received a rating of 5 Stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant change. UHG believes that 5 is outstanding performance on a measure. Even if it is a statistical decline, it is outstanding performance. By neutralizing the measure to a "hold harmless", it is putting more significance/weight on the remaining measures in the improvement measure. UHG

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<sup>1</sup> JAMA Intern Med. 2015; 175(5): 691-700

<sup>2</sup> Palliative Care Network of WI

believes that a 5 should represent a positive influence on the improvement measures and, therefore, UHG believes that a 5 should count as a significant improvement within the improvement measure calculation.

### *Data Integrity*

CMS proposes a new rule authorizing scaled reductions in Star Ratings for appeal measures in both Part C and Part D. UHG generally supports this proposal and has the following comments. First, UHG recommends that CMS exclude any data that has been determined to have issues from the cut point calculations for appeal measures. Second, CMS needs to ensure detailed results are timely provided to MA Plans and that there is a clear appeal process to ensure the results are accurate before they are applied to a MA Plan's Star Rating. Third, UHG requests CMS clarify what other sources it will use to apply scaled reductions. Finally, UHG recommends that the scaled reductions based on CMS' Timeliness Monitoring Project only apply to Part C and Part D timeliness measures.

### *Measure-Level Star Ratings*

CMS requests comments on alternative recommendations for revising the cut point methodology. UHG supports the general move to stabilize the existing Star Rating specifications through codification.

CMS proposes using a three-year average in order to reduce year-to-year variation in measure thresholds. UHG strongly supports this proposal. UHG proposes that CMS consider further stabilization by codifying threshold values calculated using a static three-year average (rather than a moving three-year average) of Star Rating years 2016-2018. UHG proposes that CMS use rulemaking to make any future threshold updates except when there are CMS-defined "non-substantive" measure methodology changes not subject to rulemaking that would therefore require quicker threshold re-calibration. In the event of such methodology changes, UHG proposes that CMS recalculate three years of industry rates under the new measure methodology, calculate three years of new thresholds, and recalculate the three-year average to derive the final new thresholds. This will also help to assess whether the methodology change has a significant impact on the rates and Stars by being able to compare the same data under old and new methodology.

CMS requested input on additional improvement adjustments that could be implemented. UHG believes measures that achieve 100% in one year and 100% in the next year should be seen as a positive impact on the statistically significant improvement level (SSIL) rather than not eligible to improve.

### *Measure Weights*

CMS requests comments on its consideration of increasing the weights of the Star Rating measures of patient experience/complaints and access. UHG supports increased weight on non-survey measures of access and complaints (appeals/IRE and CTM measures), but requests that the CAHPS and HOS survey measures of patient experience/complaints be removed, or at least be reduced in weight. The industry has long raised concerns around survey reliability, both with regard to the accuracy of survey responses and the attempts of the measure stewards to adjust for known issues in those responses and samples. UHG's concern with response accuracy stems from both internal and independent research showing a weak relationship between care received and survey response. Studies<sup>3</sup> show 10-13 percent of those

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<sup>3</sup> Various studies conducted by Alzheimer's Association

age 45 and over report they are experiencing confusion or memory loss that is happening more often or is getting worse. In addition, HOS and CAHPS surveys may be answered by family beneficiaries who may live far away without regular personal contact with the beneficiaries or their care providers, which can impact the accuracy of the data.

The CAHPS and HOS stewards have attempted to address these concerns through implementation of case mix adjustment and significance/reliability testing and adjustment. UHG is, however, concerned that these adjustments are ineffective at best, and biased at worst. The relative distribution and significance testing methodology in CAHPS, for instance, appears to be biased in a negative direction. This methodology is applied to individual CAHPS Star Rating measures: C03 - Annual Flu Vaccine, C22 - Getting Needed Care, C23 - Getting Appointments and Care Quickly, C24 - Customer Service, C25 - Rating of Health Care Quality, C26 - Rating of Health Plan, C27 - Care Coordination, D08 - Rating of Drug Plan, and D09 - Getting Needed Prescriptions. Adjustments to individual CAHPS Star Ratings measures in this latest Star Ratings year (2018) were 98% downward for the industry. A majority of these individual measures were originally 5 Stars, but since the rates were not calculated to be significantly above the national average, the individual CAHPS Star Ratings measures were adjusted downward to 4 Stars. These downward adjustments do not appropriately address the variability in CAHPS survey results. Instead, the majority of downward adjustments appear to be an unintended result of the CAHPS measures' cut point percentile levels relative to the average survey results.

UHG hopes to continue to work with CMS to look into objective alternatives to survey measures which should be added to Star Ratings in future years.

### **Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (§§ 423.100, 423.505)**

CMS proposes several changes to the current Any Willing Pharmacy (AWP) rules and guidance to try to address its concern that Part D Sponsors may be circumventing the AWP requirements and inappropriately excluding pharmacies from network participation. UHG is opposed to the regulatory constraints that CMS is proposing related to AWP requirements, as well as the proposed definitions of "retail pharmacy" and "mail-order pharmacy." Like others in the industry, UHG believes it is important that current AWP rules and guidance remain unchanged. The current requirements strike the right balance to enable network development, promote quality of care, prevent FWA (fraud, waste and abuse), and ensure beneficiaries continue to have access to affordable drugs. UHG supports the positions and recommendations relating to the AWP proposal that have been advanced by other commenters from professional associations, including the Pharmaceutical Care Management Association, and also recommends CMS withdraw its proposed changes to the current AWP rules and guidance.

UHG urges CMS to take into consideration the significant disruption and confusion that these proposed changes will have on Part D Sponsors, Part D pharmacy networks, and beneficiaries. In particular, UHG is concerned about CMS' proposal to treat all pharmacies as the same, and not allow Part D Sponsors to distinguish between pharmacy types in contracting, or exclude pharmacies on the basis that the pharmacy will not fit within the correct pharmacy type classification. Practically speaking, if a single pharmacy is more than one type of pharmacy (i.e., retail and mail), the Part D Sponsor may not be able to differentiate which set of terms and conditions should apply to a unique prescription claim, how the benefit should process, and how appropriate cost sharing should be applied. Due to this claim by claim variability, the Part D Sponsor will not be able to apply consistent industry quality standards to the

pharmacy to reduce FWA and ensure beneficiary safety. This is not only an unmanageable process, but it will also lead to beneficiary confusion because the beneficiary will have no assurance of how the prescription is being processed and what cost share applies.

In addition, if CMS does not reconsider its proposal to treat all pharmacies the same, Part D Sponsors will likely have the ability to enter into their competitor's networks, which will not only compromise competition, but allow for tacit collusion on reimbursement rates.

### **Changes to the Days' Supply Required by the Part D Transition Process**

UHG agrees with CMS' proposal to shorten the required transition days' supply in the long term care setting to the same supply required in the outpatient setting as it would streamline transition processes.

UHG seeks clarity from CMS on what it considers 'a month's supply' in the context of unbreakable packages. Currently, we allow multiple fills of drug products that are dispensed in an unbreakable package up to and over a 30 day supply to complete a transition fill because 30 days is considered the appropriate outpatient month's supply. For example, if a drug is packaged in a 28 day pack, a beneficiary could receive two fills of 28 days (total of 56 days) to fulfill transition. Based on this example, our understanding of the new proposal is that we would need to file the outpatient one month's supply as 28 days to limit a transition fill to a 28 day package. Additionally, if the filed outpatient one month's supply was 30 days, we would still need to allow 2 packages of 28 days (total of 56 days) to fulfill transition. We seek confirmation of our understanding of the proposal.

### **Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)**

UHG generally supports CMS' proposal to allow Part D Sponsors, if certain conditions are met, the ability to immediately remove, or change the preferred or tiered cost-sharing of brand name drugs and substitute or add therapeutically equivalent generic drugs without advance direct notice to CMS or beneficiaries, and at any time of the year. New generics enter the market throughout the year on a weekly basis, and UHG sees no reason to delay the immediate substitution of a generic drug for a brand name drug rather than make that change effective, for instance, at the start of the next month. The proposal also aligns with current industry practice, as the majority of State Pharmacy Boards support "mandatory generic substitution" when a generic becomes available. UHG requests that CMS confirm that this proposal would also apply to protected class generics and generic drugs of clinical concern.

Similarly, UHG agrees that Part D Sponsors would provide advance general notice to beneficiaries that these changes may occur in Part D Sponsors' formulary and other applicable beneficiary communication materials, such as the Evidence of Coverage (EOC). Following the change, Part D Sponsors would directly notify affected enrollees on the specific drugs involved and the steps beneficiaries could take to request coverage determinations and exceptions. UHG believes online posting of applicable formulary changes, including generic substitutions, is the most effective means to communicate these changes to State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists after the generic substitution is effective.

UHG urges CMS to not limit the circumstances for immediate substitution to generics new to the market. As CMS acknowledges, generic substitutions pose no threat to enrollee safety. In addition, there are many legitimate reasons for which Part D Sponsors may not immediately place a new generic on its

formulary when it first becomes available on the market, as it may not be in the best interests of the beneficiary or the Part D program. New generics may be limited in supply for many months after their market introduction. Similarly, sometimes new generic drugs do not appear on formulary reference files for months after they become available to the market, so Part D Sponsors are unable to remove the brand without submitting the generic in its place. In addition, and perhaps more importantly, until multiple manufacturers supply the market with a generic drug, which can take up to a year, their costs may not be lower for beneficiaries and the Part D program. Accordingly, provided Part D Sponsors met all of the other proposed requirements, CMS should allow Part D Sponsors to immediately remove, or change the preferred or tiered cost-sharing of brand name drugs and substitute or add any therapeutically equivalent generic drugs, not just those new to the market.

### **Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing**

UHG appreciates CMS intent to reduce costs to both Part D enrollees and the Part D program in its proposal revise the definition of generic drug to include follow-on biological products solely for the purposes of non-LIS catastrophic cost sharing and LIS cost sharing. UHG also agrees that limiting the inclusion of follow-on biological products in the proposed revised definition of generic drug to only non-LIS catastrophic cost sharing and LIS cost sharing will avoid confusion or misunderstanding that CMS treats follow-on biological products as generic drugs in all situations.

However, as previously communicated to CMS, UHG continues to urge CMS to take the position that products approved under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) will remain “applicable drugs” for purposes of the Medicare Coverage Gap Discount Program once the Food and Drug Administration (FDA) implements the “Deemed to Be a License” provision of the Biologics Price Competition and Innovation (BPCI) Act of 2009, in 2020. Under the CMS regulations, the term “applicable drug” means a Part D drug that is “(1) (i) Approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA); or (ii) In the case of a biologic product, licensed under section 351 of the Public Health Service Act (PHSA) (other than a product licensed under subsection (k) of such section 351); . . . ”. (42 C.F.R. § 423.100). Today, because biological products licensed under section 505 (b)(2) of the FDCA meet the definition of “applicable drug”, they are eligible for a 50 percent discount in the benefit coverage gap. However, if the FDA were to categorize these same products as “Deemed to Be Licensed” under section 351, subsection (k) of the PHSA in 2020, these products will effectively become biosimilar products, and will no longer be eligible to receive the 50 percent discount in the coverage gap for non-LIS beneficiaries.

UHG recommends that CMS ensure products approved under section 505(b)(2) will remain “applicable drugs” in 2020. If biosimilar products approved under section 505(b)(2) of the FDCA do not remain “applicable drugs” for purposes of the Medicare Coverage Gap Discount Program, it will likely lead to increased costs to beneficiaries and to Part D Sponsors. If these drugs are not “applicable drugs”, Part D Sponsors may choose not to place them on their formularies. If a beneficiary prefers a biosimilar and it is not on the formulary, the beneficiary will be responsible for paying the formulary exception tier copay/coinsurance, which will be higher than if the drug was on formulary. UHG encourages CMS to address this issue now in order to avoid any confusion in the marketplace on how these biologics will be treated in 2020.



## **Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences (§423.265)**

UHG supports CMS' proposal to eliminate the meaningful difference requirements between Enhanced Alternative (EA) plans offered by the same Part D Sponsor. We interpret the proposed rule to remove the obligation of gap coverage in a second EA plan because it, too, has the capability to increase plan flexibilities and increase beneficiary plan choice.

## **Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale**

### *Introduction*

UHG appreciates the opportunity to respond to CMS' request for information (RFI) on potentially requiring Part D Sponsors to include all pharmacy price concessions and a portion of manufacturer rebates through point-of-sale (POS) pricing to beneficiaries. UHG understands CMS' desire to achieve a balance between maintaining affordable premiums, managing POS costs, and having POS cost transparency. CMS believes it can achieve that balance, in part, by requiring Part D Sponsors to report all pharmacy price concessions at the POS. UHG acknowledges that requiring Part D Sponsors to report all pharmacy price concessions at the POS would (i) lower the costs of drugs at the POS for many beneficiaries; and (ii) improve drug cost transparency; however, that approach would result in increased premiums for beneficiaries. If CMS determines reporting pharmacy price concessions at the POS will strike the appropriate balance between maintaining affordable premiums, reducing POS costs, and increasing drug cost transparency, then UHG would be prepared to implement the requirement.

In contrast, any new requirement that results in reporting pharmaceutical manufacturer rebates at the POS does not result in an appropriate balance between premiums, POS drug costs, and POS cost transparency. UHG believes requiring that rebates be passed through at the POS will: (i) significantly increase premiums, (ii) not improve drug cost transparency; (iii) deteriorate the structural integrity of the stand-alone Part D program by potentially exposing Part D Sponsors to longer-term adverse selection; and (iv) decrease the amount of rebates offered, driving up costs to the Part D program. Accordingly, UHG would strongly oppose any change to the current administration of manufacturer rebates, including any requirement that Part D Sponsors apply them at POS.

Outlined below are some additional details associated with the impacts of these potential program changes.

### *Pharmacy Price Concessions*

#### Lower Cost of Drugs at Point-Of-Sale

UHG agrees with CMS that requiring Part D Sponsors to report all pharmacy price concessions at POS would lower many beneficiaries' out-of-pocket (OOP) costs at the POS, with a notable exception. It would not impact beneficiaries in plans with flat co-pays. If a beneficiary was in a coinsurance plan or a phase of the benefit where coinsurance applied, negotiated prices at the POS would be lower for generic or brand drugs and for low income or non-low income beneficiaries. The specific impact would vary depending on which phase of the benefit the beneficiary is in at the time of purchase.

### Improved Drug Cost Transparency

UHG believes CMS could achieve more transparency and less differential application of pharmacy price concessions with POS reporting. Pharmacy price concessions are less dependent on formularies and drug mix than rebates, and requiring these concessions be reported at the POS will create a more transparent comparison of OOP POS costs across competing Part D products.

### Improving Quality for Beneficiaries at the Pharmacy

UHG believes pharmacy incentive programs help to drive quality at the pharmacy for beneficiaries, creating an incentive to constantly improve beneficiaries' health outcomes through medication adherence programs and outreach. Pharmacies who perform well may receive incentive payments for high performance in these types of performance-contingent pharmacy payment arrangements.

Currently, industry-wide, pharmacy incentive programs tied to pharmacy price concessions do not have uniform quality assurance guidelines or requirements in place to drive quality across the board. UHG believes that while pharmacy incentive programs are a tool to drive quality for beneficiaries, there are alternative quality programs that have made, and could make, a significant impact on a pharmacy's performance. The strength of the Part D Sponsor and its pharmacies' quality programs are therefore not necessarily dependent on the reporting of price concessions at the POS and could be implemented in other ways.

### Increased Premiums

As CMS acknowledges on page 56428 of the proposed rule, while reporting pharmacy price concessions at the POS will result in lower POS costs for many beneficiaries and greater transparency, the trade-off will be a modest increase in beneficiary premiums. UHG believes the premium impact would be less significant than reporting rebates at the POS and that all Part D Sponsors will likely have to increase premiums.

### *Application of Manufacturer Rebates at the Point of Sale*

Requiring Part D Sponsors to report any rebates through the POS will not address the issues CMS seeks to address: reductions in POS cost-sharing, price transparency, and the competitive balance of all participants in the drug supply chain that participate in the Part D program.

Mandating POS rebates will result in significant premium increases and likely substantial decreases in rebates being offered by manufacturers, and reduce manufacturer participation in the Part D program without any increase in cost transparency to the beneficiaries. For these reasons which are discussed in more detail as follows, UHG strongly opposes the imposition of a POS rebate requirement.

### No Improvement in Drug Cost Transparency

UHG shares CMS' concern about price transparency; however, while rebates are transparent to CMS through Part D Sponsor reporting, they would not be transparent to the beneficiary even if reported at the POS. The recommendation to potentially require Part D Sponsors to report rebates at POS will ultimately disturb the competitive landscape that has driven down drug costs by reducing the amount of rebates offered by manufacturers. If CMS averaged or weighted rebates across a particular drug category or class under a POS rebate requirement, manufacturers would be driven to move toward a

standard rebate to avoid any “free rider effect” whereby manufacturers with high rebates would subsidize manufacturers with low rebates. This would distort public data and perceptions about the cost of a particular drug, providing false drug cost transparency. This would incent pharmaceutical manufacturers to regress to a lower average mean rebate in a therapy class, especially in therapy classes that require broad coverage for clinical reasons or because they are in a protected class.

For example, pharmaceutical manufacturers know Part D Sponsors must cover as many diabetic therapies as possible to increase access to diabetic medications, drive adherence, and maintain Stars performance. Requiring POS rebates would create a pool of rebate dollars for all drugs in the therapy class – here, in the diabetic therapy class. This would incent diabetic pharmaceutical manufacturers to regress to a lower average rebate in the diabetic therapy class since a Part D Sponsor cannot restrict its formulary in this class, and the manufacturer with higher rebates would not want to subsidize the lower rebated drugs.

Similarly, beneficiaries with flat co-pay plans would not experience any increase in price transparency. The only change these beneficiaries would experience under a POS rebate proposal, besides higher premiums, is that they may progress through the benefit phases at a different pace. However, as noted below, because the Part D parameters are a function of the negotiated price, any change in how quickly a beneficiary progresses through the benefit would be temporary.

Finally, requiring POS rebates represents an unfortunate shift from premium competition among Part D Sponsors to drug/drug class competition. Allowing POS rebates will still result in variable pricing across retail pharmacies because negotiated pharmacy reimbursements vary across the network. As a result, POS rebates will require beneficiaries to shop for individual drugs from pharmacies. CMS acknowledges this and advocates for putting the burden on the beneficiary to seek out the lowest cost drug and pharmacy combination; however, this is a complicated calculation that depends on many factors such as cost-sharing, coinsurance, phase of the benefit, pharmacy reimbursement rate, etc. Individual drug shopping from pharmacies would increase the number of beneficiaries with no pharmacy home. Beneficiaries would not experience the significant benefit a pharmacy home brings—helping with medication adherence and avoiding dangerous drug interactions and the potential for abuse of certain drugs. Ultimately, POS rebates and drug/drug class competition would lead to beneficiary frustration and confusion, the impression of less price transparency, and poorer health outcomes for beneficiaries.

#### Longer-Term Adverse Selection Exposure

For those beneficiaries who take mostly generic medications rather than brand drugs, requiring POS rebates will increase their premiums, with negligible POS savings for those beneficiaries. Such an increase in Part D premiums could decrease overall participation in the Part D program, particularly for healthy individuals.

Moreover, POS rebates could cause adverse selection by drug class, as beneficiaries might enroll in the plan with the highest rebate at POS with premium being less of a consideration. This could create an incentive for Part D Sponsors to avoid deep rebates on drugs that treat sick beneficiaries.

#### Decrease in Rebates and Other Cost Implications

Moving rebates to the POS may have the unintended consequence of removing incentives to provide rebates to the LIS population. Currently, pharmaceutical manufacturers offer rebates for an entire book

of business, including both LIS and non-LIS beneficiaries, in exchange for formulary placement and some measure of exclusivity. The POS rebate proposal could shift pharmaceutical manufacturers from a position of offering rebates to the Part D Sponsor in exchange for formulary placement to considering only how rebates may help the beneficiary at POS. Under the POS proposal, the value the pharmaceutical industry receives by making rebates visible to the beneficiary at POS will not be recognized for LIS beneficiaries, as those beneficiaries have cost share subsidies and no benefit phase impact to their pocketbook. The pharmaceutical industry may elect to not offer rebates on this population, unless required by law, as their specific value from rebates will be minimized. This would harm the Part D program across the board. CMS should consider the impact of the POS rebate proposal on the low income population and the potential for the proposal to increase government costs.

Additionally, the hypothesis that POS rebates will slow beneficiary progression through the benefit phases relies on the assumption that the parameters, or cut points, at which beneficiaries move across the benefit phases remains constant to the current year's standard. Sustainability of slower progression through the benefit phases year over year is not addressed in the proposed rule and is a significant concern to UHG. If it is not addressed, beneficiaries' progression through the phases may slow only temporarily – perhaps for the first two years of the proposed program – but any benefit of this proposal could quickly disappear.

#### Competitive Balance

UHG also shares CMS' concerns that a competitive advantage can accrue to one Part D Sponsor over another based on a technical difference in how Part D Sponsors' costs are reported to CMS. In looking at the Part D program, rebates are negotiated and applied similarly throughout the industry. There is more uniformity in the rebate process. UHG believes that in balancing the factors relevant to competitive advantage, requiring POS rebates could negatively impact Part D Sponsors' competitive advantage, or produce unintended outcomes, as Part D Sponsors devise variant application of rebates at the POS. This latter outcome reduces transparency and introduces the potential of new gamesmanship.

To adequately address any perceived improper competitive advantage in the rebate process, CMS would need to address all of the parties in the drug sales and distribution chain. In this RFI, CMS is not proposing to make meaningful changes in how pharmaceutical manufacturers, wholesalers or pharmacies are held accountable for the drug supply chain. Further regulating only Part D Sponsors and Prescription Benefit Managers (PBMs) to require POS rebates does not address drug manufacturing and distribution, and therefore does not adequately address competition in the industry as a whole. POS rebates reduce the incentives for one player in the supply chain (pharmaceutical manufacturers) to continue to participate meaningfully in the Part D program, creating significant imbalance in the rebate negotiation process.

#### POS Rebates In Other (Group) Markets

UHG recognizes that POS rebates may have benefits in other contexts - such as in commercial markets - apart from Part D. The market and regulatory structure surrounding commercial health insurance plans creates an environment in which POS rebates may benefit an employer or individual commercial member, but not a Part D beneficiary. For example, unlike in Part D, an employer selects POS rebate functionality on behalf of a specific employer group and rating based on the actual experience of that group. In addition, in the commercial market there are many high deductible plans where POS rebates may make a meaningful difference to member adherence, versus the relatively low deductibles in Part

D. Furthermore, rebates are not required to be reported to any regulators in the commercial context, as they are in Part D. This leads to opaque drug pricing for employer groups and the understandable desire to increase transparency to the commercial group purchaser.

#### Employer Group Waiver Plans

CMS should use its statutory authority under 42 U.S.C.S. § 1395w-132 to exempt Part D employer group waiver plans (EGWPs) from the scope of any POS rebate proposal. Part D Sponsors need to maintain consistency between commercial and retiree benefit plans to the fullest extent possible. Continued flexibility would be compromised if the Part D Sponsor had to pass through rebates at POS, potentially driving some Part D Sponsors out of the program and hindering the design of, the offering of, or the enrollment in, employer/union sponsored stand-alone prescription drug plans.

### **Improving the CMS Customer Experience**

#### **Restoration of the Medicare Advantage Open Enrollment Period (§§ 422.60, 422.62, 422.68, 423.38 and 423.40)**

UHG acknowledges that CMS proposes to implement the 21st Century Cures Act (Cures Act) establishment of a new Open Enrollment Period (OEP) from January 1-March 31 each year that allows individuals enrolled in an MA Plan to make a one-time election during the first 3 months of the calendar year to switch MA Plans or to disenroll from an MA Plan and obtain coverage through Original Medicare. UHG does not believe that the Cures Act alters a MA Plan's ability to conduct general awareness marketing during the OEP, or otherwise conduct general advertising (such as television ads). The Cures Act marketing limitation centers around "unsolicited marketing or marketing materials "sent" to individuals eligible for the OEP.

With respect to marketing mailings to OEP eligible individuals, we share CMS' concern that it would be difficult for MA Plans to exclude individuals who may be eligible and so we generally agree with using a "knowing" standard to prohibit knowingly sending marketing to these individuals. However, UHG disagrees with CMS' proposed language stating that MA Plans may not "knowingly target or send" unsolicited marketing "to any MA enrollee" during this period. The Cures Act only prohibits sending marketing to the subset of enrollees, namely those eligible for the OEP. Prohibiting all marketing mailings to any MA enrollee during the OEP could lead to a lack of beneficiary awareness/choice if MA Plans are unable to conduct general marketing to persons who are or will be eligible for an Initial Election Period (IEP) or Special Enrollment Period (SEP). Prohibiting all marketing is also contrary to CMS' expressed interest of increasing enrollment in MA Plans.

We therefore recommend that CMS modify the proposed rule language to reflect the prohibition on knowingly mailing marketing materials to *MA enrollees who are eligible for the OEP*. Consistent with the proposed 'knowing' standard, we also recommend that CMS make it clear that MA Plans and their agents cannot conduct mail campaigns that are directed to their prior year enrollees who have disenrolled from their MA coverage effective January 1 of the current year (i.e., "win back campaigns").

In addition, while we support the language limiting knowingly sending materials to eligible individuals, we are concerned that the added language prohibiting "targeting" creates ambiguity and is unnecessary. We therefore recommend removing the reference to targeting. Instead of a "targeting" prohibition, we recommend a clearer content restriction that prohibits MA Plans and their agents from referencing the

OEP in any marketing materials or encouraging enrollees to switch coverage during the OEP. As a means of comparison, Medicare Supplement carriers currently advertise the CMS Medicare Advantage Disenrollment Period (MADP) as an opportunity for enrollees to drop their MA coverage and switch to a Medicare Supplement Plan.

Finally, we recommend that CMS make it clear that MA Plans may continue to conduct IEP, SEP and general awareness marketing mailings and general advertising during the OEP (as long as those materials are not knowingly mailed to OEP eligible individuals). We also recommend that CMS continue to permit advertising that educates enrollees on enrollment opportunities for 5-Star MA Plans. Similarly, we recommend that CMS continue to permit sales agents selling MA and Part D Sponsor Plans to advertise their business during the OEP. Sales agents would validate eligibility and educate the enrollee on their enrollment window before conducting a sale.

### **Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503 and 423.504)**

UHG supports CMS' proposal to remove the requirement that MA Plans and Part D Sponsors provide compliance training to their first-tier, downstream and related entities (FDRs). We also agree with CMS' proposal to eliminate the requirement that FDRs complete the CMS compliance training modules because UHG does not believe it is a key driver of performance improvement or FDR compliance with CMS requirements. The removal of these requirements provides administrative burden relief to MA Plans, Part D Sponsors and FDRs.

To support effective adoption of these FDR related compliance program training changes, we strongly recommend CMS publish updates to Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual prior to the effective date of the revised requirements. Suggested updates include removal of FDR general compliance and FWA training and education references, as well as removal of the requirement to demonstrate that Standards of Conduct and policies and procedures were distributed to FDRs' employees (section 50.1.3 – Distribution of Compliance Policies and Procedures and Standards of Conduct). As CMS is drafting changes to Chapters 9 and 21, we would appreciate the opportunity to provide CMS detailed recommendations.

In addition, we recognize and appreciate CMS' intent to provide MA Plans, Part D Sponsors, and the FDRs with which they contract, the maximum flexibility to develop and meet requirements associated with effective compliance programs. However, we caution CMS to anticipate some MA Plans or Part D Sponsors will use this flexibility to continue burdensome oversight activities such as annual compliance training on their MA Plans or Part D Sponsors' specific materials. Further, UHG would like to caution CMS that some MA Plans or Part D Sponsors may continue to broadly apply CMS Compliance Program Effectiveness (CPE) requirements to FDRs and audit them on these requirements without regard to their applicability given the specific scope of the Medicare program requirements delegated to the FDR.

Accordingly, we recommend CMS issue additional guidance to clarify CMS' expectations and limitations of MA Plans' and Part D Sponsors' FDR oversight activities following removal of FDR compliance training requirements and underscore the expectation that MA Plans and Part D Sponsors discontinue the administration of annual compliance program training for FDRs in its current form. CMS may also mitigate this type of MA Plan or Part D Sponsor behavior by updating Chapters 9 and 21 FDR oversight references to clearly delineate the components of Chapters 9 and 21 that "flow down" to FDRs, as well

as emphasize compliance program activities the MA Plans and Part D Sponsors must demonstrate, rather than what must be demonstrated at the FDR level.

We would appreciate CMS specifying that the effective date of the removal of FDR training requirements will be no later than the 2019 plan year.

### **Revisions to Timing and Method of Disclosure Requirements (§§ 422.111 and 423.128)**

UHG fully supports CMS' proposal to allow MA Plans and Part D Sponsors the flexibility of delivering the EOC, Summary of Benefits and provider network information in electronic format in lieu of sending hardcopy mailings at the time of enrollment and annually thereafter. We are also supportive of CMS's proposal to give MA Plans and Part D Sponsors additional time to produce the EOC, provider directory, pharmacy directory, and formulary by removing the current deadline.

Consistent with CMS' proposal to direct beneficiaries to directories available electronically or to MA Plans' and Part D Sponsors' customer service to obtain a hardcopy, we recommend that CMS remove the requirement that the EOC notice must be separate and distinct from the Annual Notice of Change (ANOC) booklet. We believe that through strategic placement of the EOC notice in the ANOC booklet (e.g., at the beginning of the ANOC) and through distinct formatting/font styles, MA Plans and Part D Sponsors can achieve the same desired effect as a free-standing EOC notice, but streamline the distribution of the information in a more concise manner that is easier to reference for beneficiaries. From a print production perspective, creating standalone notices creates additional complexity that could lead to potential production issues when combining multiple freestanding documents in a single mailing. For these reasons, we recommend that the notice is an embedded component of the ANOC booklet at the MA Plan's or Part D Sponsor's discretion.

In the spirit of simplifying the beneficiary experience, UHG recommends that CMS also reconsider the volume and frequency of beneficiary mailings required of a plan. This would include allowing MA Plans and Part D Sponsors to deliver all materials electronically, in the same manner as the formulary, pharmacy directory, provider directory and, as proposed in this rule, EOC and Summary of Benefits. By reducing and streamlining the number of communications with beneficiaries through paper mailings, MA Plans and Part D Sponsors would have greater flexibility to simplify the beneficiary experience and offer more personalized effective and timely access to important health plan information with greater privacy protections.

Finally, we recommend that CMS revise the current regulations or update the CMS Medicare Marketing Guidelines, to allow MA Plans and Part D Sponsors the flexibility of combining the provider directory, pharmacy directory, abridged formulary and EOC information into one notice.

### **Revisions to Parts 422 and 423, Subpart V, Communication/Marketing Materials and Activities**

UHG fully supports CMS' proposal to narrow the definition of "marketing materials" under §§ 422.2260 and 423.2260 to only include materials and activities that aim to influence enrollment decisions. We also have the following recommendations for CMS' consideration.

UHG recommends that the current filing requirements for Non-Marketing Materials remain consistent with CMS' proposed definition of "Communication Material" (i.e., no CMS review and approval of these

types of materials). Additionally, UHG recommends that CMS model materials described in the CMS Medicare Managed Care Manual and Prescription Drug Benefit Manual also be classified as “Communication Materials” that will not require MA Plan or Part D Sponsor submission to CMS for review and approval.

UHG recommends that CMS allow the ANOC to remain a 5-day File and Use eligible document consistent with current CMS requirements. As the ANOC is a standardized CMS model document that allows only minimal modifications by plans, UHG believes there is limited risk in continuing to submit the ANOC under the File and Use process. Additionally, as a larger MA Plan and Part D Sponsor with nearly 500 plans, UHG is concerned that delays in the CMS 45-day approvals of ANOCs could jeopardize a large organization’s ability to meet the in-home deadline prior to the Annual Election Period.

UHG requests that CMS clarify how the Health Plan Management System (HPMS) marketing material code 1085 (Comprehensive Formulary) will be defined. UHG recommends that the Comprehensive Formulary be classified as a “Communication Material” that is not subject to CMS approval consistent with other the CMS “Communication Materials” contemplated in this proposed rule (e.g., the Evidence of Coverage). As the Comprehensive Formulary is based on a CMS model document that Part D Sponsors are required to adopt, UHG believes that the appropriate beneficiary protections would still be in place if classified as a “Communication Material.”

#### **Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (§§423.590 and 423.636)**

We support CMS’ proposal to change the timeframe for issuing decisions on payment redeterminations from 7 calendar days from the date the Part D Sponsor receives the request, to 14 calendar days from the date the Part D Sponsor receives the request, as this would be consistent with the standard coverage determination process. In addition, this would allow Part D Sponsors additional time to develop the case and request additional information necessary to make the redetermination decision.

#### **E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards**

CMS proposes to adopt the NCPDP SCRIPT Standard Version 2017071 and retire the current NCPDP SCRIPT Version 10.6, in order to update the electronic standards used by Part D Sponsors. UHG generally supports this change, but notes that the NCPDP SCRIPT Standard Version 2017071 does not have the functionality to capture the type of Prior Authorization the prescriber is submitting electronically. The lack of this transaction type prevents Part D Sponsors from accepting all types of electronic Prior Authorizations (ePA) that are currently available to Medicare beneficiaries.

UHG recommends that as the NCPDP SCRIPT is updated in the future, it includes the functionality to capture the “ePA type transaction” to further expand the types of Prior Authorizations, such as expedited requests via ePA, that could be submitted using electronic media.



## Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations (§§422.502 and 423.503)

We understand it is important for CMS to evaluate a MA Plans' or Part D Sponsors' performance as part of the annual application review process. We fully support CMS' proposal to change the look-back period to 12 months from the current 14 month cycle that ends the month applications are due.

UHG does, however, recommend that CMS consider a 12 month calendar year look-back period as compared to the proposed March 1 through February 28 (29 in leap years) period. For example, in the 2020 application cycle for which applications are anticipated to be due in mid-February 2019, the look-back period would be January 1 through December 31, 2018. We believe this 12 month period still permits a timely evaluation of MA Plan or Part D Sponsor performance preceding the annual application deadline and would be consistent with other MA Plan and Part D Sponsor activities and preparations that occur on a calendar year basis (e.g., bids, contracts, readiness activities). Thus, we recommend additional edits to the proposed regulatory language:

### **§ 42 CFR 422.502**

Section 422.502 is amended in paragraphs (b)(1) and (2) by removing the phrase "14 months" and adding in its place "12 month **calendar year**" each time it appears.

### **§ 42 CFR 423.503**

Section 423.503 is amended in paragraphs (b)(1) and (2) by removing the phrase "14 months" and adding in its place "12 month **calendar year**" each time it appears.

## Preclusion List—Part D Provisions

UHG supports CMS' proposal to rescind the current regulations requiring physicians and eligible professionals to enroll in or validly opt-out of Medicare in order for a Part D drug prescribed by the physician or eligible professional (or beneficiary request for reimbursement) to be covered. In general, UHG agrees that the CMS proposal of requiring Part D Sponsors to reject claims for Part D drugs prescribed by prescribers on the preclusion list will better facilitate CMS' goals of reducing prescriber burden and protecting the Medicare program and its beneficiaries from prescribers who could present risks. UHG provides the following comments and requests for clarification on the proposed provisions below.

### *Effective Date Deadline*

Given the complexity of the anticipated file specifications, as well as the coding changes, testing, and development that plans will need to do, UHG urges CMS to allow Part D Sponsors at least twelve (12) months after CMS releases its final guidance, with all of the specifications, to have the preclusion list fully incorporated into its claims adjudication systems. UHG also recommends that the deadline for full incorporation be a mid-year date, (e.g., July 1) as opposed to January 1. A mid-year deadline would allow Part D Sponsors to focus more exclusively on this important system modification.

### *CMS Updates to Preclusion List*

UHG urges CMS to consider updating the preclusion list more frequently than monthly. UHG is concerned that only updating the preclusion list monthly could lead to situations where CMS may be aware that an individual should be removed from the preclusion list, but Part D Sponsors have not yet

been notified and, as a result, claims will reject and beneficiaries may not have access to their Part D prescriptions. UHG also recommends that CMS publish the preclusion list in the same format as the current OIG List of Excluded Individuals/Entities (LEIE), and specifically, to include the prescriber's NPI number on the preclusion list file to ensure that the individual prescriber is accurately identified and appropriately included in the claims adjudication systems. In addition, UHG recommends that each updated preclusion list file be effective at least five (5) business days after Part D Sponsors receive it to allow them time to configure their claims adjudication systems with the most current version. Similarly, UHG seeks clarification from CMS on whether it will maintain an archive of the preclusion list files with the dates of enforcement. If a claim for reimbursement is received several months after the date of service, will CMS require Part D Sponsors to go back and review the preclusion list in effect at the time of the date of service?

### *Provisional Supply*

CMS indicates in its proposal that if a beneficiary has a claim from a provider on the preclusion list, it will allow plans to provide beneficiaries with one 90-day provisional supply of the drug in order to give beneficiaries notice that there is an issue with respect to future Part D coverage of a prescription written by a particular prescriber. UHG agrees with CMS that beneficiaries should receive notice and access to medications while they find a new prescriber, but UHG is concerned with the length of the provisional coverage period as it seemingly allows beneficiaries to receive access to “any” (e.g., multiple) medications written by a prescriber who is on the preclusion list, for a 90-day period of time. UHG believes that allowing the beneficiary to fill any prescriptions from a particular precluded prescriber for a 90-day time period directly conflicts with CMS' goal of protecting the Medicare program and its beneficiaries from prescribers who could present risks. This seems particularly true given Part D Sponsors are not required to continue paying for Part D drugs when the prescription is written by a provider who is excluded by the OIG and no longer in good standing with the Medicare program. As an alternative to providing beneficiaries with a 90-day provisional supply of a drug, UHG recommends that CMS instead provide advance notice of a prescriber's placement on a preclusion list and make it effective 30 days after receipt so that Part D Sponsors have time to run a report to identify affected beneficiaries and provide them with notice that they may obtain only one (1) additional prescription fill from the precluded prescriber.

If CMS finalizes its proposed provisional coverage period, UHG strongly urges CMS to issue specific guidance on how to operationalize it, and more specifically, how Part D Sponsors must reconcile the provisional coverage period with any applicable transition benefit. In the proposed rule, CMS indicates that if a beneficiary is entitled to provisional coverage, but the drug is off-formulary and the transition requirements are also triggered, the beneficiary will not receive more than the applicable transition supply of the drug, unless a formulary exception is approved. In this example, it is not clear whether CMS' expectation is that the beneficiary will only receive “a month's supply” of a transition eligible drug (unless an exception is approved), or, whether the beneficiary will also be entitled to receive additional supplies of other drugs written by the precluded prescriber during the provisional coverage period. Specific guidance from CMS on how Part D Sponsors should reconcile the relationship between the provisional coverage period and the transition benefit will help ensure that they are being applied appropriately and consistently across the industry.

CMS indicates that it is considering additional solutions for beneficiaries who try to fill an opioid prescription from a provider on the preclusion list. One alternative, “of ensuring beneficiaries have access to opioids as necessary would be to require the sponsor immediately provide a transfer to a new

provider when the first provider is on the preclusion list.” Requiring a Part D Sponsor to transfer beneficiaries from one medical provider to another is not feasible, as Part D Sponsors do not have contracts with medical providers. In addition, UHG believes that any drug-specific carve out within the program at this time would add significant complexity in administering the preclusion list as intended. Therefore, UHG recommends that CMS not pursue drug specific solutions and allow the flexibility to make decisions based on the totality of a prescriber’s activity. UHG also recommends that to the extent CMS will require Part D Sponsors to transfer beneficiaries to new prescribers, it provide Part D Sponsors with at least a 30 day notice to effectively assist the beneficiaries in the transition.

### *Appeals*

Finally, UHG requests clarification from CMS on what appeal rights a beneficiary should be permitted for alleged errors in applying the preclusion list. Under existing CMS regulations, the denial of access to a Part D drug on the basis that the provider is excluded is not a coverage determination and does not trigger appeal or grievance rights. It necessarily follows that if a beneficiary does not have access to a Part D drug on the basis that the prescriber is on the preclusion list, it is not a coverage determination and no appeal or grievance rights are triggered. Therefore, aside from verifying a prescriber was appropriately included on the preclusion list, it is not clear what appeal rights plan sponsors could provide to beneficiaries. As such, UHG recommends that CMS follow processes applicable in situations involving an excluded/sanctioned prescriber and not provide any appeal rights. UHG further recommends that any beneficiary complaint about a denial due to an individual or entity included on the preclusion list be treated via the grievance process, as there is no beneficiary liability and as such, nothing for the beneficiary to appeal.

### **Preclusion List --- Part C/Medicare Advantage Cost Plan and PACE Preclusion**

UHG supports CMS’ proposal to rescind the current provisions in 42 C.F.R. section 422.222, which state that “providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization.”

Overall, UHG agrees with CMS’ proposal that “an MA Plan shall not make payment for an item or service furnished by an individual or entity that is on the newly proposed and defined ‘preclusion list’”. We firmly believe greater focus on individuals or entities that demonstrate problematic behaviors, versus screening for all individuals and entities “to be enrolled in and in an approved status with Medicare”, is more efficient and aligns with CMS’ broader intent to reduce administrative burden. This will permit MA Plans to concentrate their resources on preventing MA Plan payment for items and services furnished by providers and suppliers that could pose a greater risk to beneficiaries and the Medicare program. UHG has the following comments on the proposed framework.

### *Combined Preclusion List for Parts C and D*

UHG supports CMS’ proposal to create and define one preclusion list for Parts C and D consisting of certain individuals and entities that are currently revoked from Original Medicare under 42 C.F.R. section 424.535 and are under an active reenrollment bar, or have engaged in behavior determined to be detrimental to the best interests of the Medicare program.

### *Effective Date Deadline*

Consistent with the comments regarding the preclusion list for Part D, given the complexity of the anticipated file specifications, as well as the coding changes, testing, and development that MA Plans will need to do, UHG urges CMS allow MA Plans at least twelve (12) months after CMS releases its final guidance, with all of the specifications, to have the preclusion list fully incorporated into its claims adjudication systems. UHG also recommends that the deadline for full incorporation be a mid-year date (e.g., July 1) as opposed to January 1. A mid-year deadline would allow MA Plans to focus more exclusively on this important system modification, while being able to adequately prepare for annual readiness implementation activities at the beginning of the calendar year.

### *Preclusion List Format and Updates*

UHG recommends CMS publish the preclusion list in the same format that the current OIG LEIE database is published. This would include the file extension (i.e., .csv) and placement on a public domain for download capability. The LEIE list is published as a cumulative file with two monthly supplements – new exclusions and reinstated individuals/entities. UHG recommends that CMS maintain a file that tracks the history for those individuals and entities that are reinstated on the cumulative file, as this facilitates a more efficient process for updating provider records and processing claims. In addition, UHG recommends using the same LEIE record layout that currently captures the individual's and entity's demographics. UHG strongly recommends CMS include the provider's NPI in the preclusion list to allow MA Plans to more accurately match individuals and entities loaded in MA Plans' systems to ensure approved organization determinations are not issued for those individuals or entities on the preclusion list.

### *Payment Denials*

To mitigate the administrative burden and beneficiary confusion that would result if CMS required MA Plans to retroactively deny payment for health care items or services furnished prior to an individual's or entity's inclusion on the preclusion list, UHG strongly recommends that the Final Rule maintain the proposed language that payment denials would apply only to health care items or services furnished on or after the date the individual or entity was added to the preclusion list. UHG also recommends CMS provide MA Plans with a 30 day advance notice of the addition of individuals or entities to the preclusion list to align with provider termination notification requirements and to assist MA Plans with identifying and notifying beneficiaries of the individual's or entity's preclusion status.

### *Additional Beneficiary Protections*

CMS solicits comment on whether additional beneficiary protections, such as notices to enrollees when an individual or entity that has recently furnished services or items to the enrollee is placed on the preclusion list and temporary coverage approval when an individual or entity is first placed on the preclusion list, but is in the middle of a course of previously covered treatment, should also be included in these rules. UHG recommends not providing temporary coverage when an individual or entity is placed on the preclusion list, even if the beneficiary is in the middle of the course of treatment or services were approved via the organization determination process. The placement of an individual or entity on the preclusion means that the individual or entity has committed an act that has resulted in them no longer being able to be enrolled in Medicare and thus render services. Allowing for payment

after placement on the preclusion list could expose beneficiaries to unnecessary risk. In addition, there is no current temporary coverage allowed for individuals or entities that are placed on the LEIE list.

With regard to beneficiary notification, UHG urges CMS to consider permitting MA Plans to follow existing processes, including but not limited to, the termination of a contracted MA Plan provider and subsequent notification to the beneficiary. Upon submission of a claim from an individual or entity that is on the preclusion list, it would be denied and the beneficiary would not have any liability for the claim, yet the beneficiary would receive an explanation of benefits notifying the beneficiary of the claim denial and reason. If the claim denial were related to a contracted provider who was then terminated from a MA Plans' network, the beneficiary would be notified of that and the reason.

#### *Encounter Data and NPI*

CMS proposes to require that for data equivalent to Medicare fee for service data, known as MA encounter data, that MA Plans must submit a National Provider Identifier (NPI) in a billing provider field on each MA encounter data record. CMS intends to use the NPI to identify individuals and entities that CMS may include on its Part C preclusion list.

UHG would like to confirm that the NPI is intended for encounter data submitted to CMS via Encounter Data System (EDS), and not the abbreviated format via the Risk Adjustment Processing System (RAPS). We suggest these changes to the proposed Section 422.310 (d)(5):

(5) For data described in paragraph (d)(1) of this section as data equivalent to Medicare fee-for-service data, which is also known as MA encounter data submitted to CMS **via the Encounter Data System (EDS)**, MA Plans must submit a NPI in a billing provider field on each MA encounter data record, per CMS guidance.

#### *Complaint Process – Beneficiary and Provider*

UHG does not support the establishment of a separate appeal and notice process for beneficiaries related to the preclusion list. If an individual or entity is included on the preclusion list and is a MA Plan contracted provider, MA Plans should follow the existing provider termination process and subsequent beneficiary notifications would be sent. In the case of a claim submission and subsequent denial, UHG proposes that CMS allow beneficiaries to file a grievance, as there is no beneficiary liability and as such, nothing for the beneficiary to appeal.

UHG supports CMS offering a separate appeals process (with CMS) for individuals or entities identified for the preclusion list should the individual or entity not agree with CMS' decision to include them on the preclusion list.

#### **Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152)**

UHG acknowledges and commends CMS for its proposal to remove the requirement at 42 CFR 422.152 related to Quality Improvement Projects (QIPs). We concur with CMS that the QIPs are duplicative of activities MA Plans are already conducting to meet other needs and requirements (e.g., Chronic Care Improvement Programs, quality activities evaluated by the Star Ratings measures). MA Plans will be able to focus efforts on those health improvement activities and take steps to reduce redundancies, which supports reduction in administrative burden for MA Plans and CMS.

## Reducing Provider Burden – Comment Solicitation (medical records)

CMS requests feedback on the nature and extent of the burden on providers of producing medical record documentation and suggestions for addressing the burden. We understand this is a solicitation for comment only, and we offer the following thoughts.

### *MA Plans Need for Medical Records*

One reason MA Plans request medical records is to comply with CMS requirements to submit complete diagnostic data for risk adjustment purposes and to ensure accurate payment from CMS. For professional claims, medical providers are generally reimbursed based on the CPT code submitted on the claim, and reimbursement is not determined based on the diagnoses submitted. If a diagnosis is not submitted on the claim, MA Plans request copies of medical charts to identify diagnoses for risk adjustment. This typically happens one time after the year is complete to minimize the burden of requesting and producing the chart. We are supportive of working with providers to submit medical records in a consistent manner.

In addition to risk adjustment, MA Plans have numerous reasons for requesting medical records related to the care and treatment of our beneficiaries, such as: clinical pre-authorizations of services requested, post-discharge care management, HEDIS, gap in care closure, claims payment decisions, payment integrity activities (e.g., detection and remediation of fraud, waste, abuse, and errors), and processing appeals and grievances. The number and frequency of requests varies significantly, as they are triggered by specific events.

UHG does not believe regulatory or sub-regulatory standards for chart retrieval and attestation functions are necessary or would be helpful. CMS currently mandates the collection of complete diagnosis data and allows MA Plans flexibility to incorporate standards for data collection into their contracts with providers. CMS should not interfere with the relationship between MA Plans and contracted providers. MA Plans have the incentive to negotiate reasonable chart production requirements for their network providers, and providers can address any concerns during such negotiations. CMS should not impose one-size-fits-all requirements.

MA Plans also have every incentive to reduce provider abrasion related to chart requests. To this end, UHG is conducting multiple pilots to improve the processes and interactions around requesting and accessing providers' electronic medical records. One pilot focuses on the exchange of large medical records. We also have a pilot where the provider gives us access to their electronic medical records, and we can retrieve the medical records of our members for clinical authorization, payment integrity, appeals and reconsiderations, as well as claims payment. These pilots are being conducted with privacy considerations and requirements in mind to ensure members' data is protected. UHG is also reviewing the elements of the provider records to identify those that are common across multiple functional (operational) areas in order to develop more standard, consistent requests that would enable us to better reuse a medical record internally across those areas.

In addition, UHG is exploring additional ways to reduce provider abrasion. We generally request medical records to be produced within 45 days, yet allow flexibility to providers who may need more time to respond. We are also working with providers to be more efficient in our requests, such as requesting complete copies of a member's medical record at one time instead of requesting parts of the record multiple times and using complete records for multiple purposes, rather than re-requesting records.

Further, we try to give a provider one list of all the members for whom records are needed, such as during HEDIS and risk adjustment chart reviews.

### *Challenges to the Adoption of a More Efficient System*

UHG supports greater collaboration within the industry to promote providers' use of electronic medical records and movement toward a common, standard data exchange due to the wide variation experienced today. UHG currently actively participates in several industry forums and groups. These activities drive toward consistency and efficiency in exchange of information. UHG believes there could be value in having a set standard and file lay-out across providers. This consistency would have benefits beyond MA and could result in improved clinical integration and patients' outcomes. We believe CMS has the same goals.

Although MA Plans are interested in developing a more efficient system to access medical records while minimizing provider abrasion, unfortunately, there are currently obstacles to achieving these outcomes that we would like to share with CMS. For example, providers who have customized electronic medical record systems at a provider-level require each interaction between a MA Plan and the provider/provider group to be a separate implementation project between the provider/provider group, the MA Plans or the providers' delegate. Many providers have multiple electronic medical record systems requiring access to each system to collect a single beneficiary's entire history. Often, records are not located in one place or in a similar format creating a challenge for efficient collection. There is also wide variation in medical records formats, which makes it challenging for MA Plans to load data into their systems. Moving to a standard electronic medical record format would increase MA Plan's operational efficiency. It could lead to less burdensome requests and retrievals for providers, reduce costs, as well as the time for providers to respond to MA Plan's requests. Thus, we encourage CMS to support industry and stakeholder collaboration to promote further development of standard electronic medical record formats and exchanges.

Finally, the industry also has some current limitations using medical records from the Health Information Exchanges where MA Plans are required to prove the source of the medical record to CMS, (i.e., chain of custody), which is important for acceptance of the records for HEDIS. If there were more standardization of exchange and format of medical records, it would increase acceptance of the records MA Plans provide in their reporting.

## **Implementing Other Changes**

### **Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements (§§ 422.2420 and 423.2430)**

*Fraud Prevention Activities as Quality Improvement Activities (QIA) (§§ 422.2420, 422.2430, 423.2420, 423.2430)*

CMS proposes to remove the current exclusion of fraud prevention activities from quality improvement activities (QIA) at 422.2430(b)(8) and 423.2430(b)(8), to expand the definition of QIA at 42 CFR 422.2430 and 42 CFR 423.2430 to include *all* fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery and to no longer include in incurred claims the amount of claims payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses at §§ 422.2420(b)(2)(ix) and 423.2420(b)(2)(viii).

UHG's understanding of the proposed language is that MA Plans will no longer be able to include the amount of claims payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses in the calculation of incurred claims, and that MA Plans will be able to include all fraud prevention, detection, and reduction activities as QIA.

Fraud recoveries are a small part of the fraud related activities that MA Plans engage in, and a significant amount of time and resources are focused on payment integrity efforts that include fraud prevention and detection activities as well. These efforts save the Medicare program more than a billion dollars annually. The return on investment for the program is significant, and CMS should encourage these activities. UHG supports the changes CMS is proposing and believes it will incent MA Plans to spend additional resources on the prevention and detection, or "front end" activities, to improve payment integrity and mitigate fraud.

Currently, the regulation prohibits the inclusion in QIA of activities "designed primarily to control or contain costs." An argument could be made that fraud prevention activities are primarily attempts to control costs. If the regulation excludes fraud reduction that is a form of cost control, MA Plans would be uncertain as to what should be included in the calculation and fraud prevention would be disincented. For this reason, we believe that the exclusion should be limited, and we recommend the following regulatory changes:

**42 CFR 422.2430(b) Exclusions.** Expenditures and activities that must not be included in quality improving activities include, but are not limited to, the following:

(1) Those that are designed primarily to control or contain costs **other than those related to fraud reduction.**

**42 CFR 423.2430(b) Exclusions.** Expenditures and activities that must not be included in quality improving activities include, but are not limited to, the following:

(1) Those that are designed primarily to control or contain costs **other than those related to fraud reduction.**

#### *Medication Therapy Management (MTM) (§§ 422.2430 and 423.2430)*

CMS proposes to modify §§ 422.2430 and 423.2430 and add a new paragraph (a)(4)(i) to specify that all MTM programs that comply with § 423.153(d) and are offered by Part D sponsors, including MA Plans offering MA-PD plans are QIA.

UHG supports CMS' clarification and proposed regulatory changes to explicitly include MTM program expenditures in the MLR numerator as QIA-related expenditures.

#### *Changes to Medicare MLR Reporting Requirements (§§ 422.2460 and 423.2460)*

CMS proposes to reduce the amount of MLR data that MA Plans must report by limiting the reporting to four data fields: organization name, contract number, adjusted MLR, and remittance amount.

UHG appreciates and supports CMS' recommended changes to reduce the annual MLR reporting requirements. UHG does not anticipate that this change will result in a modification to its current processes given that it will still be required to retain documentation support MLR amounts and respond to any related audits. In addition, UHG would appreciate CMS confirming these changes in MLR



reporting requirements mean that CMS will no longer be creating and providing detailed report instructions and templates, or conducting MLR desk reviews. If yes, UHG expects that CMS will update the MLR filing instructions to reflect the reduced reporting burden, and MA Plans will no longer need to comply with the current voluminous reporting documentation and worksheets, including support for non-claims costs.

#### *Minimum Threshold for QIA*

On November 2, 2017, HHS published its proposed 2019 Notice of Benefit and Payment Parameters, which sets out standards for health insurance issuers participating in the individual and group health insurance markets (82 FR 51052). In this NPRM, HHS proposed to amend the commercial MLR formula to recognize a minimum QIA expenditure equal to 0.8% of earned premiums. HHS stated that the use of a minimum QIA cost amount was based on its observations that between 2011 and 2015, issuers that reported QIA expenses reported spending on average, a consistent percentage of premium, on total QIA of approximately 0.7 % in 2011, and 0.8% from 2012 through 2015. (82 FR 51114) HHS also proposed that commercial issuers could request a higher QIA percentage based on documentation submitted to HHS. In essence, the 0.8% is proposed as a minimum regulatory threshold for QIA in the commercial business. The purpose of this minimum threshold percentage would serve to reduce the reporting burden of complying with the MLR requirement.

We think a minimum threshold for MA Plans would similarly reduce the burden for MA Plans choosing to report only this amount. We recommend that CMS permit the same rule for MA to keep the programs aligned. The percentage should be based on the average QIA for MA Plans plus fraud reduction efforts. Alternatively, CMS could establish a minimum threshold for QIA based on historical data and count fraud reduction as a separate item to be included in the numerator.

#### *Remove the Enrollment Penalties in the Medical Loss Ratio (MLR) Rules for MA (42 CFR 422.2410(c) and (d), 42 CFR 423.2410 (c) and (d)*

MA Plans are required to report, track, and modify their business approach to meet a government prescribed MLR, a mechanism that was used in the Affordable Care Act (ACA) to encourage health plans to provide high value to enrollees.

The MLR requirement for MA imposes an enrollment freeze if a MA Plan misses the MLR requirement of 85 percent for three consecutive years. If the MA Plan misses for five consecutive years, the MA Plan is terminated. A strict application of the MLR rule has the unintended consequence of penalizing highly-rated MA Plans that receive quality bonuses. This can mean beneficiaries can be denied access to plans recognized for quality and efficiency.

Additionally, the complicated CMS bid process contains numerous uncertainties that MA Plans must project over a two-year period, including change in population, actual medical expense trend, and risk score trend. Bid process timing is further compounded by the MLR time frame – when data becomes available and when benefit decisions have to be made – and can cause MA Plans to miss the MLR requirement.

Additional program changes in Risk Adjustment, Health Insurance Tax and the Encounter Data System create greater uncertainty because they are not considered when making MLR adjustments. For example, if MA Plans bid assuming the insurer fee applies to next year and the insurer fee is

subsequently repealed or further delayed, MLR calculations should be adjusted to reflect the impact of the insurer fee on the MLR based on what the MA Plan assumed in its bid pricing.

Finally, the Part D program uses risk corridors allowing CMS to share in the risks undertaken and any profits earned by Part D Sponsors. For this reason, the additional MLR process is unnecessary and wasteful, which is likely why the statute does not require CMS to apply MLR rules to Part D. Moreover, Part D's much lower revenue structure compared to MA makes an 85 percent MLR impracticable. The MLR calculation in Part D inexplicably excludes programs (Low Income Stability payments and Coverage Gap Discount), which should be included.

The receipt of Stars bonuses can make compliance with MLR requirements more complex and less predictable. CMS should conduct a demonstration and delay implementation of any three- or five-year enrollment penalties resulting from MLR calculations, while still assessing rebates from the MA Plan for contracts that do not meet annual thresholds. This demonstration project would maintain MA Plan and beneficiary choice. Alternatively, CMS could calculate MLR at the parent organization level, as increasing the number of beneficiaries included in the calculation alleviates the changes MA Plans experience in Star Ratings quality bonuses. Finally, if a MA Plan fails to meet the 85 percent MLR threshold due to increased payments from Star Rating bonuses, CMS should not apply the enrollment penalties, yet MA Plans would still need to return the rebate amount.

### **Physician Incentive Plans - Update Stop-Loss Protection Requirements (§ 422.208)**

This Administration has repeatedly expressed that it prioritizes reducing administrative burden and complexity through regulatory reform. In particular, the Administration is targeting regulations that are outdated, that impose costs that exceed benefits, and that create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies. (See 2/24/2017 Presidential Executive Order on Enforcing the Regulatory Reform Agenda.)

While we appreciate CMS's attempt to update the physician incentive plan (PIP) regulation at 42 CFR § 422.208, this proposed rule falls short of achieving the Administration's goals. The proposed rule substantially expands the length of the regulation and applicable requirements and does little to alleviate the regulatory burdens that were created when the regulation was first created almost 20 years ago. In fact, the proposed rule does not touch most of the existing regulation, including those aspects that multiple parties have repeatedly asked CMS to change. The proposed rule is also inconsistent with the sophistication of physician incentive arrangements currently in the marketplace and those CMS supports through its Quality Payment Program and its own risk arrangements with physicians. The changes being proposed to the PIP regulation further complicate an already complicated regulation and add technical jargon that will be challenging for most to understand (including the physicians who will need stop-loss insurance that complies with the proposed regulation). To help support CMS's efforts to update this regulation, to make it more effective for its intended purpose, and to align it with related regulatory reform initiatives, UHG respectfully submits the following recommendations and questions for CMS's consideration.

UHG also respectfully recommends that CMS consider additional, more comprehensive updates to the PIP regulation beyond what is currently being proposed. To that end, we propose that CMS gather stakeholder input from both MA Plans and physician groups before finalizing revisions to the PIP regulation. UHG offers to work with other MA Plans and stakeholders to analyze, research, and develop specific recommendations to submit to CMS for consideration. We believe this would result in an

improved regulation, while maintaining the protections for MA enrollees that the PIP regulation was intended to provide.

*The PIP regulation does not require MA Plans to pay for stop-loss insurance.*

The PIP regulation imposes an obligation on MA Plans to assure that appropriate stop-loss protection is in place if a physician incentive arrangement places the physician at substantial financial risk. (See 42 CFR 422.208(c)(2) and (f)(1) (“The MA organization must assure...”).) For various well-supported reasons, CMS deliberately used the word “assure” during the regulation’s development to allow the responsibility of paying for stop-loss protection to be a negotiable issue between MA Plans and physician groups. (See 65 FR 40170, 40241; 61 FR 69034, 69043-44.)

We note, however, that in at least two places in CMS’s commentary on the proposed rule, CMS states that the MA organization must provide the stop-loss protection “at the MA organization’s expense.” (82 FR 56336, 56461 and 56482.) This position is contrary to the language in the regulation and earlier CMS guidance. To avoid creating any ambiguity, disrupting existing contractual arrangements, and shifting an enormous financial burden, we request that CMS clarify that paying for PIP stop-loss protection is a matter of negotiation between MA Plans and physician groups, and that the MA Plan’s obligation is to assure that stop-loss protection consistent with the PIP regulation is in place.

#### *Update Deductible Limits and Codify Methodology*

UHG applauds CMS for updating the deductible limits and codifying the methodology so that limits can be updated more frequently. UHG has previously submitted comments to CMS requesting an update to the deductible limits because after nearly two decades of remaining static, they were artificially low and resulted in cost-prohibitive premiums. UHG supports CMS moving the deductible limits out of the Code of Federal Regulations and issuing them in sub-regulatory guidance, as this will allow updates to occur more frequently in order to trend with changes in medical costs and utilization.

CMS asked for comments regarding whether it should finalize a specific schedule for updating the deductible tables. UHG supports establishing a specific schedule for regular updates and recommends an update occur every two or three years, given the dynamic nature of medical costs and utilization. Pricing for stop-loss insurance is based on annual claims data so an update to the deductible limits every two or three years is reasonable, while not being unduly burdensome. UHG supports publication of the updates to the deductible tables in the Draft Call Letter.

CMS also solicited comments on the proposed regulatory text concerning the methodology and how the tables will apply. UHG submits the following comments in response to that request.

*Potential payments includes both direct and referral services.*

UHG believes the proposed methodology rests on an erroneous understanding of “potential payments” and this mistake generates deductible limits that are too low. The PIP regulation defines what the term “potential payments” means and that definition includes payments for referral services, as well as payments for the physician’s direct services. The regulation states that potential payments “means the maximum payments possible to physicians or physician groups including **payments for services they furnish directly, and additional payments based on the use and costs of referral services**, such as withholds, bonuses, capitation, or any other compensation to the physician or physician group.”

(Emphasis added.) This definition is consistent with the governing statute, which requires stop-loss protection if the plan places a physician or physician group at substantial financial risk “for services not provided by the physician or physician group”. (See 42 U.S.C. 1395w–22(j)(4)(A)(ii).)

The regulation’s potential payments definition is critical to determining the threshold for substantial financial risk. The PIP regulation provides that substantial financial risk “occurs when risk is based on the use or costs of referral services and that risk exceeds the risk threshold.” (42 CFR 422.208(d)(1).) That threshold under the regulation is “25 percent of potential payments.” (42 CFR 422.208(d)(2).) The 25 percent risk threshold is therefore required to be of potential payments and thus both referral and personally performed services.

In contrast, the proposed rule appears to define potential payments to exclude payments for referral services. For instance, proposed paragraph (f)(2)(iv)(B)(4) states:

The distribution was used to obtain, with 98 percent confidence, the point at which a multi-specialty group of a given panel size would, through referral services, lose more than 25 percent of the net income derived from services that the physicians personally rendered.

A similar statement is made in paragraph (f)(2)(vii)(A) (“Both the numerator and denominator are for physician services that are rendered by the physician or physician group.”). The commentary explained that CMS “used projections of total income based on services provided personally by individual physicians and directly by physician groups because that is how we interpret ‘potential payments’ as defined in the existing regulation.” (82 FR 56336, 56462.) Given that this is contrary to the existing PIP regulation, this error should be fixed to accurately reflect what potential payments include. Furthermore, this misunderstanding of what is included in “potential payments” produces incorrect deductible limits. To use a simplified example, if only the income of \$100 for personally rendered services is used for the threshold calculation, then the risk threshold is \$25. But if the physician’s income of \$125 for both personally rendered services and referral services is used, then the risk threshold is \$31.25. A higher deductible limit will result in a less costly stop-loss insurance premium and ultimately a significant cost savings when purchasing stop-loss protection on a per-patient basis.

We therefore request that CMS update its methodology described in the proposed rule to ensure that potential payments includes both direct and referral services consistent with the governing statute and the existing regulation’s definition. This would require changing the proposed language for (f)(2)(iv)(B)(4) and (f)(2)(vii)(A), as well as updating the deductible limits that CMS set forth in Tables 13 and 14.

*Clarifying that “global capitation” means at risk for professional and institutional referral services.*

In the proposed rule, CMS has stopped using the term “single combined” when referring to full risk arrangements (that is, arrangements where the physician is at risk for both professional and institutional referral services) and is using “global capitation” instead. However, global capitation is not defined and its scope is unclear. The proposed rule uses various terms to describe the concept, such as “globally capitated patients,” “global capitation arrangement,” “capitation arrangement,” and “global risk.” We note that the PIP regulation already defines capitation as:

[A] set dollar payment per patient per unit of time (usually per month) paid to a physician or physician group to cover a specified set of services and administrative costs without regard to the actual number of services provided. The services covered may include the physician's own services, referral services, or all medical services.

It is not clear which services are included in the new term “global capitation.” In its commentary to the proposed rule, CMS states that it “refers to capitations to physicians that include services the physicians do not render as ‘global capitation.’” (82 FR 56336, 56482.) This explanation is broad enough to encompass capitation arrangements that only cover referral services for institutional services or those capitation arrangements that only cover referral services for professional (that is, non-institutional) services. This is not how the term “global capitation” is generally understood in the industry. The industry typically uses global capitation when referring to capitation arrangements that include referral services for *both* professional and institutional services. A global capitation arrangement therefore puts the physician at financial risk for both professional and institutional referral services.

UHG therefore urges CMS to revert to using the term “combined” or “combined professional and institutional” rather than “global capitation” in order to promote a clear and common understanding of what arrangements are subject to the new regulatory requirements.

This is particularly important because the proposed rule repeatedly emphasizes that the tables and methodology set forth in the new rule apply solely to global capitation arrangements. (Note that one such limitation refers simply to “capitation arrangements” and may be missing the “global” modifier; see (f)(2)(iv)(A).) In order to comply with the proposed rule, MA Plans need to know which payment arrangements to apply to the new tables and methodology.

Similarly, MA Plans need to understand what stop-loss protection is permitted for all other, non-global capitation physician incentive arrangements. The proposed rule states, no less than three times, that the tables and methodology do not apply to anything but global capitation arrangements. (See (f)(2)(iv)(A) and (B), and (f)(2)(v)(A).) It instructs “that other stop-loss insurance needs to be used for non-capitated arrangements” (and presumably for non-global capitated arrangements, yet this is not clear). Despite these repeated admonishments, the proposed rule does not explain how deductible limits are to be calculated for these non-global capitation physician incentive arrangements. UHG respectfully requests that CMS identify in the proposed rule what methodology will apply for those arrangements.

#### *Non-Risk Patient Equivalents Included in Panel Size*

UHG supports allowing the calculation of patient panel size to include more of the patients the physician or physician group provides services to because that panel size more accurately reflects the risk a physician or group is managing. But UHG has concerns relating to the new non-risk patient equivalents (NPEs) provision and favors updating the pooling conditions in section (g) or collapsing the option to pool into section (f).

#### *Defining NPEs and Distinguishing from Pooling Conditions*

NPE is a new term in the proposed rule that UHG believes should be defined in the regulation due to lack of clarity. The commentary provides one example of a non-risk patient, which is a Medicare fee-for-service patient. (See 82 FR 56336, 56464.) In contrast, the proposed rule counts any patient that is a “non-global risk” patient as an NPE, which would seem to mean that any patient who is not covered

under a global risk arrangement may be counted. (See (f)(2)(vii)(A).) As a result, the proposed rule's more expansive understanding of who constitutes an NPE raises questions about how the new NPE provision interacts with the pooling conditions under section (g) of the existing PIP regulation because a patient covered under a non-global risk arrangement could be counted as an NPE, but could also be counted under the pooling provision.

Moreover, the proposed rule uses NPEs as an acronym first in (f)(iii)(B), but does not explain what the acronym is until later in (vii)(A). Defining the term in section (a) of the regulation would help prevent confusion when the term appears later in section (f).

Other proposed language likewise raises questions about how NPEs would apply in conjunction with the five pooling conditions under section (g). Section (f)(2)(vii) provides that "commercial and Medicaid patients who are at global risk and in the same stop-loss risk pool may be included" in determining the number of "global risk patients." Are MA Plans to assure compliance with the requirements of this provision, as well as section (g) or is satisfying one adequate? What does "same risk pool" mean in this context and does it overlap with any of the five pooling conditions? Assuming clarification of these concepts, CMS should update the pooling conditions by simplifying and reducing them to two conditions that would be clearly described within the regulation: (1) the risk terms are comparable across the patients being pooled, and (2) the patients are in the same risk pool.

### *Operational Challenges*

Another problematic aspect of NPEs relates to the data used to calculate them. Proposed provision (f)(2)(vii)(A) states that the number of NPEs is calculated in part based on "the projected annual aggregate payments to the physician or physician group for non-global risk patients." MA Plans do not possess that information for their contracted physicians or physician groups and would need to rely on the physicians to share it. However, physicians would be extremely unlikely to share that income-related information with payers. Because MA Plans hold the ultimate responsibility to assure compliance with the PIP regulation, how would MA Plans be expected to obtain and verify that information? Are attestations from physicians concerning the calculated number of NPEs sufficient? If CMS intends to publish the final rule allowing NPEs, we respectfully request that CMS provide further guidance on how MA Plans can satisfy their regulatory obligations given the high likelihood that physician groups will not share certain patient and income information.

### *Actuarially Equivalent Arrangements*

UHG supports the proposed actuarially equivalent option under the Special Insurance provision. It introduces a flexibility for compliance with the PIP regulation that was not available before.

### *Additional Suggestions*

The proposed regulatory language needs clarification in certain sections. In addition to the recommendations above, UHG offers the following:

- Add the following language as indicated: "(iii)(A) Stop-loss protection must cover 90 percent of costs of referral services above the deductible or an actuarial equivalent amount of the costs of referral services that exceed the per-patient deductible limit. The single combined deductible, for policies that pay 90 percent of costs of referral services above the deductible.... ."

- Add a dollar sign when using the term DGCP+100,000 so that it states DGCP+\$100,000 and is therefore clear what unit is being applied. (See (f)(2)(iii)(B) and (f)(2)(v)(B).)
- Remove the following language in (vii)(B) in the proposed regulation on what insurance coverage is available in the market as an inappropriate topic to be included in the Code of Federal Regulation or alternatively, establish a minimum patient panel size level if CMS believes there should be no substantial financial risk and thus no stop-loss protection at that level: “The lowest deductible shown in the tables described in paragraphs (f)(2)(iii) and (v) of this section would generally not be available for sale from an insurance company.”

### **Changes to the Agent/Broker Compensation Requirements (§§ 422.2274 and 423.2274)**

UHG agrees that removing the language at 42 C.F.R. sections 422.2274(b)(2)(i), 422.2274(b)(2)(ii), 423.2274(b)(2)(i), and 423.2274(b)(2)(ii) provides clarity. UHG agrees that the language is no longer relevant given the current renewal compensation rate limits are not based on the initial payment, but instead are based on the current fair market value cut-off amounts published annually by CMS.

### **Changes to the Agent/Broker Requirements (§§ 422.2272(e) and 423.2272(e))**

UHG supports the deletion of 42 C.F.R. sections 422.2272(e) and 423.2272(e). It is UHG’s experience that unlicensed sales of MA Plans and Part D Sponsors plans are generally due to oversight and are not the result of an intentional act. The elimination of these provisions will allow MA Plans and Part D Sponsors to develop disciplinary guidelines that are appropriate and avoid overly punitive results (e.g., termination of agent agreement from a single unlicensed sale).

## **Other**

In addition to the comments and recommendations above, we are providing the following recommendations for CMS to consider for future rule-making.

### **Beneficiary Communications – Undeliverable Mail**

We recommend that CMS re-evaluate its expectations specific to undeliverable beneficiary mail. When the United States Postal Service returns mail due to incorrect or inaccurate mailing addresses, we continue to send information according to CMS expectations. However, we believe that this creates unnecessary administrative burden that will not improve the beneficiaries' likelihood of accessing the health plan materials and it may create greater risk for privacy exposure. We recommend instead that the MA Plans and Part D Sponsors be required to work with beneficiaries to obtain more accurate contact information through additional outreach and provide health plan materials to the proper address when that is confirmed.

### **Independent Review Entity - Coding and Administrative Simplification**

We recommend the Independent Review Entity (IRE) decide cases in line with the coding standards set forth in national coverage determinations (NCDs) and local coverage determinations (LCDs) and direct providers to follow the NCD and LCD Reconsideration processes to add additional conditions for coverage. We have observed inconsistencies in how the IRE interprets the NCDs and LCDs when reviewing cases on appeal.

Additionally, UHG recommends that MA Plans have an opportunity to request repeal reversals made at the IRE level. Where providers have access to the Medicare Appeals Council and an administrative law judge review, MA Plans are not allotted similar opportunities for a tiered level of review.

## **Auditing and Monitoring**

UHG recommends CMS revisit its auditing and monitoring oversight and provide the industry with a simplified approach by establishing benchmarks to evaluate MA Plan and Part D Sponsor performance. Benchmark performance should be based on a statistically significant passing rate of which those rates are published to the industry in advance to inform MA Plans' and Part D Sponsors' process improvement and remediation activities.

Further, we recommend CMS establish expectations that its auditors and affiliated audit firms regularly, and timely, provide MA Plans and Part D Sponsors the detailed results of the audit and/or monitoring activity performed in order for the MA Plans and Part D Sponsors to use that information to drive action and improve outcomes. Reducing the overall timeline of the audit and/or monitoring activity will allow MA Plans and Part D Sponsors to take meaningful action to address any issues identified. When the results are provided in concert with the next cycle of review, there is not enough time for the MA Plans and Part D Sponsors to effect changes to improve outcomes in the current, subsequent activity. Additionally, when audit and monitoring protocols and guidance are routinely changed, the administrative burden that results in revising the organization's approach to audit preparedness compromises the ability to focus on correcting any previously identified issues and executing compliant audit outcomes for the next cycle of reviews.

There should also be a clear, meaningful process provided for MA Plans and Part D Sponsors to review the findings and dialogue with CMS on any discrepancies between CMS findings and internal MA Plan's and Part D Sponsor's reviews. Finally, we ask CMS to ensure their oversight approach aligns priorities with important points in a plan life cycle, allowing them to focus on executing operations during key times like the AEP and new plan year.

UHG welcomes the opportunity to discuss the auditing and monitoring approach further with CMS and offer additional context for our recommendations.

## **Broaden Definition of "employment-based retiree coverage" for EGWP Products**

CMS currently has a narrow definition of "employment-based retiree coverage" for determining eligibility for an EGWP plan. [See definitions below from the CFR § 422.106 and the Medicare Managed Care Manual, Chapter 9, Section 30.1] One of the key elements of the October 12, 2017 Executive Order Promoting Healthcare Choice and Competition Across the United States was to direct the Secretary of Labor to expand access to Association health plans (AHPs) by expanding the definition of an "employer" for these purposes.

On January 5th, 2018, the DOL published a proposed rule changing the definition of "employer" under ERISA and expanding the use of Association Health Plans (AHPs). This proposed rule has been developed in consultation with HHS, CMS, the Department of the Treasury, and the Internal Revenue Service. We suggest CMS adopt a similarly expanded definition for "employment-based retiree coverage" which



would align with the DOL approach to determining whether there is a sufficient common economic or representational interest or genuine organizational relationship for there to be an employer group or association capable of sponsoring an ERISA (or in this case an EGWP MA) plan on behalf of its employer members.

We recommend that CMS similarly broaden the definition of employment-based retiree coverage to allow greater flexibility for associations and other types of organizations to collectively purchase EGWP MA plans. This would facilitate broadening the offering of these valuable plans to more Medicare beneficiaries. This expanded definition could still be limited to employment-related associations, meaning that a retiree would need to be a retiree of an employer that would belong to the association. For example, retired restaurant workers could seek coverage through a restaurant association sponsored benefit plan. To achieve this end, we recommend that CMS amend the applicable regulations as follows:

- Supplement § 422.106 (d) (6) to include a § 422.106 (d) (6) (v), and read as follows: “An employment-based association plan, such as one sponsored by the National Restaurant Association, where the retiree’s membership in the association is related to their employment.”
- Delete the last sentence from the Medicare Managed Care Manual, Chapter 9, Section 30.1: “However, an association of farm bureaus would not meet this test if membership in a farm bureau were not exclusively based on former employment by these farm bureaus. (See §422.106(d)(4) through (6)).”

CMS could provide even greater flexibility if it put more emphasis on defining “employment based” coverage rather than focusing on the employer, as the term itself is explicitly focused on “employment” not “employer”, which implies eligibility based on employment status. This would still align with the approach of determining whether there is a sufficient common economic or representational interest for eligibility through an industry association, regardless of whether the employer is a member of the association, and would allow Medicare beneficiaries that are sole proprietors (e.g. an individual farmer) to be eligible for membership through an agricultural trade association. To achieve this result, CMS could:

- Supplement § 422.106 (d) (6) to include a § 422.106 (d) (6) (vi), and read as follows: “An employment-based association plan, such as one sponsored by an agricultural trade association, where the retiree’s membership in the association is related to their individual industry employment (including individual industry contribution) rather than solely focusing on an employer’s membership to an association.”
- Delete the last sentence from the Medicare Managed Care Manual, Chapter 9, Section 30.1: “However, an association of farm bureaus would not meet this test if membership in a farm bureau were not exclusively based on former employment by these farm bureaus. (See §422.106(d)(4) through (6)).”

## Step Therapy and Site of Service

We request that CMS review the past interpretation of regulations and sub-regulatory guidance requiring MA Plans to cover all benefits covered under Original Medicare, except hospice. We believe that some of the current interpretations are overly restrictive. Specifically:

- Step therapy requirements, and other controls allowed under Part D, should be allowed for Medicare Part B drugs. Requiring use of the safest, best proven and most cost-effective treatment first can help beneficiaries achieve the best possible outcomes while keeping costs down for all beneficiaries. Implementing such protocols does not deny any beneficiary coverage that is available under Original Medicare, since drugs with such requirements are covered once the requirements are met; rather it ensures that beneficiaries obtain the safest possible care in a cost effective manner. In addition, the FDA has recently expedited approvals for several very high cost drugs used to treat rare diseases. While providing quick access to unique drugs for rare diseases is important, allowing controls for Medicare Part B drugs based on the known scientific evidence (published trials) assures drugs are utilized in those patients who have demonstrated benefit from the drug and prevents waste of utilization where no benefit has been demonstrated.
- CMS should permit MA Plans to mandate site of service requirements for specific elective services. For example, MA Plans may specify that elective outpatient MRIs may only be obtained in freestanding facilities, not hospital-based facilities, unless there are no freestanding facilities available or it is clinically necessary for the beneficiary to use another setting. Requiring use of the most cost-effective locations when available does not prevent beneficiaries from obtaining covered services yet can help keep costs down for all beneficiaries.

## Rewards and Incentives

CMS should allow reduced cost sharing for certain covered benefits, specific tailored supplemental benefits and/or lower deductibles as an incentive for beneficiaries who participate in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources and create a new safe harbor under the anti-kickback rules similar to that permitted for accountable care organizations. This would allow MA Plans to better engage all beneficiaries in taking an active approach in managing their own health and potentially avoiding serious illnesses. Allowing different types of incentives than currently available can help MA Plans promote better adherence within at-risk populations, such as those at-risk for flu and pneumonia due to low vaccination rates. Different types of incentive programs can drive better adherence where current incentive programs are not sufficiently effective. This flexibility should include MA Plans being allowed to offer:

- Rewards in the form of lowering/waiving co-pays, coinsurance or health plan premiums.
- Rewards for medication adherence and other activities related to Part D benefits.
- Program designs that appeal to the human nature of loss aversion (e.g., the plan “gives” the beneficiary the entire reward up front, and the beneficiary must take action to avoid “losing” it).
- Sweepstakes/raffles as a way to offer rewards.