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Humana

March 5, 2018

Mr. Demetrios Kouzoukas, Principal Deputy Administrator and Director, Center for Medicare
Ms. Jennifer Lazio, F.S.A., M.A.A.A., Director, Parts C & D Actuarial Group,
Office of the Actuary, Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244
Submitted via regulations.gov

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

Dear Mr. Kouzoukas and Ms. Lazio:

This letter is in response to the Centers for Medicare and Medicaid Services (CMS) request for comments on the 2019 Part C and Part D Payment Policies and 2019 Call Letter advance notice rule as issued on February 1, 2018.

Humana Inc., headquartered in Louisville, Kentucky, is a leading health care company that offers a wide range of insurance products and health and wellness services that incorporate an integrated approach to lifelong well-being. As one of the nation's top contractors for Medicare Advantage (MA) with approximately 3.5 million members and Medicare Prescription Drug Plans (PDPs) with approximately 5.1 million members, we are distinguished by our near 30-year, long-standing, comprehensive commitment to Medicare beneficiaries across the United States. These beneficiaries – a large proportion of whom depend on the Medicare Advantage program as their safety net and many in underserved areas – receive integrated, coordinated, quality, and affordable care through our plans.

The Medicare Advantage program remains the largest, most successful, and comprehensive, integrated care delivery model in Medicare. MedPAC estimates MA payments in 2017 were equal to what those beneficiaries would have cost in traditional Medicare on average.[1] Stanford University economists found that MA plans negotiated at least 4.7 percent savings on hospital

[1] MedPAC, "Medicare Advantage program: Status report," December 8, 2016.

services compared to the traditional Medicare prices.[2] Moreover, Medicare Advantage plans provide copay reductions, Part D premium reductions, and/or supplemental benefits (e.g., dental) that are not provided by traditional Medicare. Milliman has calculated the "value add" of these services above traditional Medicare as being worth on average over $76 per member per month in 2016.[3]

The Medicare Advantage program furthermore delivers higher quality scores on a host of clinical quality measures[4,5] and better outcomes versus traditional Medicare in rates of hospital readmissions and racial disparities.[6] Medicare Advantage has been found to be associated with lower risk of preventable hospitalizations and National Bureau of Economic Research economists have found that enrollees in Medicare Advantage have fewer overall hospitalizations.[7] Several recent studies have shown that increasing Medicare Advantage enrollment changes how medicine is practiced in a local market and can even be associated with positive effects on traditional Medicare (the "spillover effect").[8] For example, Harvard researchers found that between 2007 and 2014, in counties in the highest quartile of baseline Medicare Advantage penetration, MA was associated with a significant decrease in traditional Medicare spending growth ($154 annually per 10-percentage-point increase in Medicare Advantage). The authors concluded that these findings suggest that Medicare Advantage growth may be playing a role in moderating FFS Medicare costs.[9]

Successful innovations in integrated care management for growing and multiple, complex chronic conditions and value-based payment models – including home and community-based

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[2] Laurence Baker, M. Kate Bundorf, Aileen Devlin, and Daniel Kessler," Calculating Medicare Advantage/Fee-For-Service Price Differences Is Harder Than It Looks," November 28, 2016 and Baker, Laurence C., et al. "Medicare Advantage Plans Pay Hospitals Less Than Traditional Medicare Pays." Health Affairs 35.8 (2016): 1444-1451.

[3] Report available online at http://us.milliman.com/uploadedFiles/insight/2016/2016-medicare-advantage-industry.pdf

[4] Brennan, Niall MPP & Shepard, Mark BA. "Comparing Quality of Care in the Medicare Program." *American Journal of Managed Care,* November 2010. Vol, 16 No. 11, p. 841-848.

[5] Ayanian, John Z. Landon, Bruce E. Newhouse, Joseph P. et. al. "Medicare Beneficiaries More Likely to Receive Appropriate Ambulatory Services in HMOs than in Traditional Medicare." *Health Affairs,* 32, no. 7 (2013): 1228-1235.

[6] Lemieux, Jeff, MA; Cary Sennett, MD; Ray Wang, MS; Teresa Mulligan, MHSA; and Jon Bumbaugh, MA. "Hospital Readmission Rates in Medicare Advantage Plans." *American Journal of Managed Care.* February 2012. Vol. 18 No. 2, p. 96-104 and : Li, Yue, et al. "Does Medicare Advantage Reduce Racial Disparity in 30-Day Rehospitalization for Medicare Beneficiaries?." Medical care research and review: MCRR (2016).

[7] Basu, Jayasree, and Lee Rivers Mobley. "Medicare managed care plan performance: a comparison across hospitalization types." *Medicare & Medicaid research review* 2.1 (2012) and Mark Duggan, Jonathan Gruber, and Boris Vabson. *The Efficiency Consequences of Health Care Privatization: Evidence from Medicare Advantage Exits*. No. w21650. National Bureau of Economic Research, 2015.

[8] See: Baicker, Katherine, Michael E. Chernew, and Jacob A. Robbins. "The spillover effects of Medicare managed care: Medicare Advantage and hospital utilization." Journal of health economics 32.6 (2013): 1289-1300; Callison, Kevin. "Medicare Managed Care Spillovers and Treatment Intensity." Health economics (2015); and Howard, Steven W., et al. "Chronic Disease Prevalence and Medicare Advantage Market Penetration Findings From the Medical Expenditure Panel Survey." Health Services Research and Managerial Epidemiology 2 (2015): 1-6.

[9] Johnson, Garret, et al. "Recent Growth In Medicare Advantage Enrollment Associated With Decreased Fee-For-Service Spending In Certain US Counties." Health Affairs 35.9 (2016): 1707-1715

care, post-acute care transition programs, and behavioral economics-driven member engagement programs – powered by advances in new technology and member engagement – underpin these program outcomes. Stability in appropriate funding is essential to prevent disruptions in coverage for millions of seniors and disabled individuals, while financing continued advancements in the delivery of clinical care, healthier outcomes and lower system-wide costs—the very payment and delivery models that the Agency is seeking to advance in Original Medicare. We urge the Agency to use its authority to ensure fair and sustainable payment and policy standards that meet the needs of more than one-third of Medicare beneficiaries who choose Medicare Advantage.

Summary of Humana's Key Issues and Recommendations

- **Encounter Data Weighting –** We do not believe the original intent of the encounter data system was to specifically reduce aggregate MA payments. However, the President's Fiscal Year 2019 Budget specifically states that the proposed transition to encounter data is designed to reduce MA plan payments. The HHS Budget in Brief estimates that the transition to encounter data will reduce plan payments by approximately $11.1 billion over 10 years. Accordingly, Humana does not support a purposeful reduction to MA payments via encounter data; Humana therefore opposes any increase in encounter data weighting.

- **Normalization Factors** - The preliminary 2019 normalization factor for the CMS-HCC model used in payment years 2017 and 2018 is 1.041, and for proposed "Payment Condition Count" model it is 1.038. Additionally, CMS is proposing to maintain the Payment Year 2018 "linear slope" methodology to project the 2019 normalization factors for all models. We are concerned that the proposed approach of compounding an annual growth rate derived from a linear model is inappropriate. We recommend that CMS use 7 years of data rather than 5 when applying the proposed methodology. The effect of using 7 years of data rather than 5 would be to lessen the impact that the 2016 outlier data point would have on the normalization factor.

- **Employer Group Waiver Plans –** Humana supports the continuation of the bid-to-benchmark ratios applied in calculating the 2018 MA EGWP payment rates when calculating the 2019 MA EGWP payment rates **if** CMS addresses the significant member population differences between Individual and EGWP plans. These differences include a higher rate of Preferred Provider Organization (PPO) plans among EGWPs, higher utilization of out-of-network providers in EGWPs, higher end of life costs in EGWP plans, differences in geographic distribution, and differences in average risk scores between EGWP and Individual plans.

- **MA ESRD Payment –** For a number of technical reasons detailed in the body of the letter, Humana believes that the ESRD benchmarks are not truly representative of the actual costs for MA plans. Moreover, CMS is not proposing to recalibrate the ESRD model, which will reduce risk scores. We are very concerned about underpayment

relative to costs for ESRD beneficiaries in MA. Accordingly, we urge CMS to base the ESRD rates on a five year average of costs and to not move forward with the proposed ESRD model recalibration.

- **Health Related Supplemental Benefits -** Humana applauds CMS's proposal to allow plans to offer enhanced supplemental benefits that can enhance beneficiaries' quality of life and improve health outcomes. Humana has a strong commitment to tackling the social determinants of health.[10] Allowing MA plans to expand supplemental benefits will have positive impacts on social and environmental determinants and ensures a holistic approach to enhancing health outcomes for the Medicare population.

- **Drug Utilization Review Controls –** Humana strongly supports CMS's goal of reducing opioid overutilization in the Medicare population. We have implemented several programs aimed at managing our members' opioid use. While we applaud the intent of the agency's proposal to require all plan sponsors to uniformly implement a hard claims edit when a beneficiary's cumulative daily maximum morphine equivalent (MME) reaches or exceeds 90 MME, we are concerned that the current proposal conflicts with the Centers for Disease Control and Prevention's (CDC) Guidelines for Tapering Opioids for Chronic Pain.

As always, we value this opportunity to provide comments and are pleased to answer any questions you may have with respect to the comments below. We hope that you consider our comments as constructive feedback aimed at ensuring that together we continue to advance our shared goals of improving the delivery of coverage and services in a sustainable, affordable manner to Medicare beneficiaries, focused on improving their total health care experience.

Sincerely,

Mark A. Newsom
Vice President, Public Policy

[10] We urge CMS to watch our YouTube video on food insecurity https://www.youtube.com/watch?v=-txAGGa2Adc and to review our Bold Goal population health efforts at http://populationhealth.humana.com/

Advance Notice Part 1: Taking Into Account the Number of Conditions of an Individual

CMS interprets the 21st Century Cures Act to "mean that, in addition to the increase in the risk score that occurs today for each additional condition in the payment model that a beneficiary has, the CMS-HCC risk adjustment model should also account for the number or count of conditions a beneficiary has." To implement this requirement CMS proposes two different options: 1) The Payment Condition Count model All; or 2) The Condition Count model. The Payment Condition Count model is based on the conditions in the 2017 CMS-HCC model and the Condition Count model is based on all conditions (all ICD-9 diagnosis codes).

Comments: Humana agrees with the CMS interpretation of the 21st Century Cures Act. However, we believe that Congress should not have required CMS to add to the complexity of the risk adjustment model for such a small incremental gain in predictive precision. Ideally, this concept would have been publicly studied rather than required. We support the Payment Condition Count Model proposal for the following reasons:

- **Congress did not expressly direct CMS to use every diagnosis code within the International Classification of Diseases (ICD) framework** – If Congress had wanted the All Condition Count Model, they would have expressly stated to individually count each and every ICD code;

- **The Payment Condition Model yields more stable risk scores** – CMS noted in the Fact Sheet, the Payment Condition Model is more stable than the Condition Count Model; and

- **The Payment Condition Model is more accurate** – as CMS stated, the Payment Condition Model "improves the risk adjustment model by improving accuracy across deciles of predicted risk, by either decreasing over-prediction observed in some deciles or decreasing under-prediction in other deciles." By contrast, the Condition Count Model "reduces predicted accuracy for beneficiaries with fewer than 5 chronic conditions, and reduces predictive accuracy across almost all deciles of predicted risk (both low and high)." Congress instructed CMS to make improvements to risk adjustment. Since the Condition Count Model actually reduces accuracy, whereas the Payment Condition Model improves it, the choice is clear under that set of statistical facts. Moreover, conditions that are currently included in the payment model are, by design, those that are predictive of treatment cost; therefore, including conditions that are not currently in the payment model by definition, should not yield improvement in payment accuracy.

However, Humana has concerns with the limited transparency concerning this proposal. CMS has not provided the necessary information to validate the impact of the proposed model changes. Specifically, CMS has not provided the crosswalk of ICD-9 codes to the new model HCCs, nor has CMS made available the model software for the proposed

changes. The rationale offered heretofore by CMS when requesting the ICD-9 crosswalk has been that plans will be paid based on ICD-10 submissions; therefore, the only crosswalk they intend to provide is for ICD-10 codes to the new model HCCs. We believe this view does not take into account some critical factors. First, in the Advance Notice Part I, CMS acknowledges that the model was calibrated on 2014 ICD-9 diagnosis coding data, because CMS did not expect the diagnosis coding patterns in 2015-2016, the first years of ICD-10, to be sufficiently stable for use in model calibration. Therefore, the ICD-9 crosswalk to the new model HCCs appears to be available to CMS, as it would have been needed for model calibration purposes. Second, the plan-level risk score data supplied by CMS, which is to be used by plans to evaluate the impact of the model changes, was based on 2015 diagnosis data, which relied on ICD-9 coding for the majority of the year. While we appreciate that this information was intended to be helpful, we are unable to: 1) validate these plan-level risk score calculations without the ICD-9 crosswalk; and 2) use them to isolate the impact of the model change alone, as the information includes both the model change as well as different diagnosis sources (RAPS in the 2017 model, EDS + RAPS IP in the Payment Condition Count model).

Humana sought to replicate CMS's results using 2015 diagnosis information by converting the ICD-10 codes in the proposed 2019 ICD-10 to HCC mappings back to ICD-9 using a crosswalk based on the General Equivalence Mappings (GEMs). This calculation yielded a result that is significantly different than the range of contract-level risk score changes illustrated in the Part 1 Advance Notice fact sheet.[11] It is possible that our programming of the new model is somehow faulty, and that is the reason for the discrepancies, but we cannot verify without the additional information.

Because we are unable to validate CMS's plan-level results, we have concerns that the proposed model changes may have an unfavorable impact on plan risk scores, and not the positive impact implied by the 2019 Advance Notice Part 1 Fact Sheet. We also note that failing to provide the ICD-9 crosswalk and model software is counter to the stated intent "to provide greater transparency in our proposed changes to the Part C risk adjustment model for 2019 as we implement the risk adjustment requirements added by the 21st Century Cures Act, as well as to provide a meaningful opportunity for stakeholders to review and fully evaluate the substantive proposals in their entirety."

Advance Notice Part II

CMS Fact Sheet on the 2019 Medicare Advantage and Part D Advance Notice and Draft Call Letter

For the past several years, the fact sheet has included estimates of industry-wide coding trends. For example, in the 2019 fact sheet, CMS stated that "for 2019, CMS expects the underlying

[11] See https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-12-27.html

coding trend to increase risk scores, on average, by 3.1%."[12] For bid years 2016, 2017, and 2018, the fact sheet included estimates of 2.0%, 2.2%, and 2.5%, respectively.

> **Comments:** CMS should detail the methodology used to determine the estimated coding trends cited in its annual fact sheets. For greater transparency and to be consistent with regulatory best practices, we would recommend including a full regulatory impact analysis for the Advance Notice and Draft Call Letter in the document itself, rather than, providing high level impacts in the separate Fact Sheet.

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

CMS continues to provide timely data to the industry about potential future changes impacting the program, including preliminary estimates of growth rates and potential changes in bid instructions as outlined in the Actuarial User Group calls.

> **Comments**: We thank CMS for its past efforts to improve the timeliness and level of detail regarding the factors used in the calculation of projected growth rates. We encourage CMS to continue providing more granular information regarding methodologies and analysis related to the development of the county benchmarks. Specific to this year's notice, we note that the increase in the Total USPCC is greater than the increase in the FFS USPCC, suggesting that payments to Medicare Advantage plans are expected to increase at a higher rate than payments to FFS Medicare providers. An explanation of the specific factors and their magnitude that contribute to differences between the Total USPCC and FFS USPCC would be helpful.
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> Additionally, we have the following general questions regarding the development of MA benchmarks and the corresponding development of risk scores:
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> Part A Only: Risk Model Calibration
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> There are potentially contradictory definitions in the Advance Notice for New Enrollees. On page 3, a New Enrollee is defined as "those with less than 12 months of Part B enrollment in the data collection year." However, the footnotes on pages 38, 39, 50, 62 state that "for payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the data collection year." We respectfully request that CMS provide clarification on how a New Enrollee is defined for purposes of the model calibration.
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> Hospice Impact on AGA and USPCC
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> For payment year 2012, OACT began excluding all claims for beneficiaries in Hospice status as described on p. 14 of the 2012 Advance Notice. [13] Humana assumes that this

[12] See https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-02-01.html

[13] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2012.pdf

aspect of the USPCC methodology has not changed since that time. As there is no mention of how the Hospice member months and associated risk scores are handled, can OACT please describe what exclusions, if any, are made in the AGA factor and USPCC calculation for these beneficiaries in terms of their member months and associated risk scores?

Attachment II. Section B. Calculation of Fee for Service Cost

CMS is proposing to calculate county FFS costs in a manner that is effectively consistent with the methodology used for 2017 and 2018. For Puerto Rico in particular, CMS will continue to include claims and enrollment only for beneficiaries with both Part A eligibility and Part B enrollment for all five years (2012 – 2016). While most Medicare beneficiaries are automatically enrolled in Part B and must opt out to decline it, beneficiaries in Puerto Rico must take affirmative action to opt-in to Part B coverage. CMS believes it is appropriate to adjust the FFS rate calculation in Puerto Rico used to determine MA rates so that it is based on beneficiaries who are enrolled in both Part A and Part B in order to produce a more accurate projection of FFS costs per capita in Puerto Rico. CMS is also seeking comment on whether to apply an adjustment in 2019 to Puerto Rico standardized FFS costs to account for the disproportionate percentage of beneficiaries that have no Medicare claim reimbursements per year.

Comments: We thank CMS and officials at the Department of Health and Human Services for addressing concerns raised by stakeholders regarding FFS data and MA benchmarks in Puerto Rico. Special considerations are necessary given the unique nature of the Medicare program in Puerto Rico. For example, as of February 2018, MA program penetration is 71% in Puerto Rico, which is more than twice the rate in the United States mainland.[14] Moreover, 90% of all beneficiaries enrolled in both Parts A & B in Puerto Rico (approximately 581,000 beneficiaries) are in MA.

Humana supports the CMS adjustments to the FFS rate calculations in Puerto Rico. We further suggest that CMS adopt the same methodology of including only beneficiaries enrolled in both Parts A and B for determining standardized county FFS costs nationwide, not just in Puerto Rico. As MA penetration continues to grow, it is leaving fewer and perhaps less representative beneficiaries upon which to calculate FFS spending in certain counties. Over time, a larger share of Medicare beneficiaries are joining MA and a larger share of those remaining in FFS are not enrolling in Part B. From July 2009 to July 2015, the share of beneficiaries in MA rose from 24% to nearly 32%, while the percentage of beneficiaries remaining in FFS with both Part A and Part B dropped from 89% to 87%.[15] This drop has had a direct impact on MA benchmarks because FFS beneficiaries enrolled only in Part A have, on average, lower costs than beneficiaries with Part A and B. In its March 2017 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) found that Part A spending for beneficiaries enrolled in Part A and B all year average 8% more than average Part A spending for

[14] CMS MA State/County Penetration - February 2018 file.
[15] MedPAC, Report to the Congress: Medicare Payment Policy (March 2017), p. 361.

beneficiaries enrolled in Part A (with or without Part B).[16] Beneficiaries in Part A who choose not to enroll in Part B are also, on average, healthier than those who buy Part B. MedPAC found that the average risk score of beneficiaries enrolled in both Part A and Part B is 6% higher than all beneficiaries enrolled in Part A (with or without Part B).[17]

If the growth in MA penetration continues as expected, there will be an even smaller share of beneficiaries in FFS buying Part B coverage in future years, resulting in some counties having MA benchmarks based on FFS baseline spending inaccurately measured with a low proportion of beneficiaries enrolled in both Part A and Part B. In order to address this issue, *we recommend that CMS adopt MedPAC's recommendation to calculate MA benchmarks using FFS spending data only for beneficiaries enrolled in Part A and Part B.*[18]

Attachment II. Section D. ESRD Rates

CMS proposes 2019 ESRD Medicare Advantage benchmarks based on FFS dialysis reimbursement and enrollment data from each state for the years 2012-2016. CMS also proposes to incorporate enhancements to the ESRD data system and projection methodology, including the ability to apply repricing adjustments to the CY2019 ESRD rates.

Comments: The MA benchmark for beneficiaries with ESRD is calculated using a less refined methodology than that used for other Medicare beneficiaries. As a result, the MA benchmark for an ESRD beneficiary in any one plan is not a true representation of the expected FFS cost of for that beneficiary. While less than 20% of Medicare beneficiaries diagnosed with ESRD were enrolled in an MA plan in 2015,[19] we expect that number to increase significantly in 2021, when ESRD beneficiaries will be given far more flexibility to join MA plans as a result of the 21st Century Cures Act.

In advance of 2021, and as part of a mandated report on MA ESRD payment rates, we request that CMS begin studying methodologies to improve the accuracy of the MA ESRD benchmarks. For example, we recommend that CMS examine the following issues highlighted in a recent white paper prepared by the actuarial firm Milliman:[20]

- ***ESRD rates are statewide rates as opposed to county based*** – Provider fee schedules under traditional Medicare are area-adjusted at a more granular level than the state level used for MA ESRD benchmarks. As a result, state benchmarking may not be a good representation of the expected FFS cost for

[16] Ibid, p.362
[17] Ibid.
[18] Ibid.
[19] CMS Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information.
[20] See http://us.milliman.com/uploadedFiles/insight/2017/ESRD-MA-Benchmark-201709.pdf

ESRD beneficiaries in the MA plan's service area depending on the location within the state where ESRD beneficiaries receive their care;

- ***The MA benchmark for ESRD beneficiaries is not adjusted for the plan's quality score –*** The ESRD prospective payment system includes a quality component that rewards dialysis providers for providing quality care. However, an MA plan's payment for ESRD beneficiaries, which includes non-dialysis services, does not account for the comparable metric, its Star rating; and

- ***ESRD historical revenue shortfall is classified as a mandatory supplemental benefit in the bid process –*** The benefit expense for Medicare-covered benefits for ESRD beneficiaries is grossed up to reflect administrative expenses and profit and then compared to the CMS revenue for these beneficiaries. Any shortfall is categorized as a mandatory supplemental benefit. This process reduces funding for ESRD beneficiaries.

We applaud CMS for proposing to use five years of historical claims data when setting ESRD rates rather than the existing method of using only one year of data. In addition, we request that CMS work collaboratively with plans to develop strategies to improve the ESRD risk adjustment model in advance of the Report to Congress on risk adjustment, mandated by Section 17006(f)(2)(ii) of the 21st Century Cures Act, which is due by no later than December 31, 2018.

Attachment II. Section G. MA Employer Group Waiver Plans

CMS is proposing to continue waiving the bidding requirements for all MA EGWPs. In connection with this waiver, for 2019 CMS is proposing to continue an alternative payment policy using bid-to-benchmark ratios for individual market plan bids. CMS is soliciting comment on whether to solely use individual market plan bids to calculate the bid-to-benchmark (B2B) ratios, or to continue to use the B2B ratios applied in calculating the 2018 MA EGWP payment rates when calculating the 2019 MA EGWP payment rates. Additionally, a new adjustment has been proposed to account for the difference in the proportion of beneficiaries enrolled in Health Maintenance Organization (HMO) vs. Preferred Provider Organization (PPO) plan types between EGWPs and individual-market plans. CMS also proposes to continue prohibiting MA EGWPs from buying down Part B premiums for their enrollees using rebates.

Comments: While we are not opposed to the waiving of the bidding requirements for EGWPs, we want to ensure that EGWP payments are appropriate relative to the populations that they serve. To this end, Humana supports the continuation of the B2B ratios applied in calculating the 2018 MA EGWP payment rates when calculating the 2019 MA EGWP payment rates, **if** CMS addresses the population differences between markets. Specifically, by using only the individual market plan bids from 2018 to calculate the B2B ratios, CMS would significantly underfund EGWP plans as detailed in our comments below. As CMS noted in the 2017 Advance Notice, the average bid in 2014 for non-employer plans was 86 percent of their benchmarks, while EGWPs

submitted bids that averaged 95 percent.[21] Characteristics of EGWP plans that result in higher B2B ratios versus Individual plans include the following:

- **Product mix differences: Individual plans are more likely to be a HMO plan type, whereas EGWPs are more likely to be PPOs** – In the January 2018 CMS Monthly Enrollment by Plan file, among plans with more than 10 enrollees, 75% of Individual plans are HMOs and only 58% of EGWPs plans are HMOs. On an enrollment basis, 74% of the Individual plan enrollment is in HMOs, but only 27% of the EGWP enrollment is in HMOs. [22] As MedPAC has noted, HMO plan types generally have lower bids relative to the plan benchmark.[23] Thus, due to the higher concentration of HMO members, B2B ratios produced using Individual MA bids will be inherently lower than corresponding EGWP ratios. Including Individual MA ratios in payments to EGWPs without adjusting for the differences in enrollment by product type will substantially understate the revenue necessary to cover expected original Medicare benefits for EGWPs. Specifically, an evaluation of Humana data shows that when adjusting for differences in the product mix of Individual vs. EGWP plans, of which more than 80 percent of enrollees of the latter were in Local PPO plans in 2016, we find that our 2016 B2B ratio difference closes from 9% to 3%.

  For the reasons outlined above, we support the product adjustment as proposed in the 2019 advanced notice. We believe this to be a critical and necessary adjustment to ensuring that the EGWP payments are appropriate relative to the populations that they serve. We recommend a blended adjustment for all EGWP plans, instead of an adjustment for each specific EGWP product. We believe the proposed approach will help with CMS payment stability and will recognize changes in product proportion for future payment years. However, product mix is only one of several characteristic differences between EGWP and individual plans;

- **Differences in the geographic distribution of EGWP members** – Humana's EGWP members in Local PPO plans in 2016 were located in counties that had higher FFS Medicare costs relative to their payment benchmarks in comparison to Individual members. We believe that geographic differences between EGWP and Individual members may contribute to the differences in cost and recommend that CMS study this further;

- **Higher end of life costs that result from higher rates of persistency among EGWP enrollees** – Retirees enrolled in Humana EGWP MA plans have a higher

[21] See http://medpac.gov/documents/reports/mar14_entirereport.pdf
[22] Humana analysis of CMS Monthly Enrollment by Plan - January 2018 available online at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Enrollment-by-Plan-Items/Monthly-Enrollment-by-Plan-2018-01.html
[23] MedPAC,"Report to the Congress, Medicare Payment Policy," March 2016

average age as compared to Individual MA plans. This age difference may be a result of a greater propensity for EGWP plan retirees to stay on their same EGWP MA plan until death, since group retiree health insurance is generally supported by employer/union contributions toward the premium, which provides an incentive for retirees to maintain continuous coverage under the group plan. This aspect of group coverage differentiates EGWP plan members from Individual MA plan members who may be more likely to shop annually in a constantly changing marketplace with respect to premiums and benefits. We have found that "end of life" medical expenses in EGWP plans are higher than in Individual plans. As in our comments last year, we urge CMS to study whether mortality rate differences between EGWP and Individual plan members contribute to higher EGWP plan costs.

CMS responded in the 2017 final rate notice that "the CMS-HCC risk adjustment model takes the age and health status of beneficiaries into account. Therefore, we would expect that if this were the case, risk scores for MA EGWPs would be higher on average than those in the Individual MA market." However, as CMS is aware, risk scores include both a demographic component and a component based on medical diagnoses. Comparing the demographic component of Humana's 2016 risk scores, excluding the Medicaid add-on factor, we do in fact see that this component is higher for EGWP plans than for Individual, as would be expected for an older population. The fact that risk scores in total are lower for EGWP plan members as compared to Individual plan members is confirmed by an examination of industry-wide actual bid data from Worksheet 1, as outlined later in this section;

- **Higher out-of-network (OON) utilization in EGWPs** – The EGWP "waiver" provision recognizes that retirees are often geographically dispersed, and allows for a higher proportion of out-of-network utilization than would typically be seen in Individual MA plans. Accordingly, a larger percentage of EGWP plan utilization occurs outside the plan's network service area as compared to Individual plans. For Humana, the proportion of out-of-network utilization in 2014 was nearly double for EGWP Local PPO plans than for Individual Local PPO plans. CMS requires that providers that are out-of-network are paid according to the FFS Medicare fee schedule, while Medicare Advantage Organizations (MAOs) may negotiate for lower rates for in-network providers. Therefore, all else being equal, plans that have a greater proportion of utilization occurring out of network may incur higher costs (though no higher than FFS Medicare) for the same set of services;

- **Allowed Cost Differences** – The primary component of the plan bid is the projected total net medical expense for Medicare covered services at original Medicare levels of cost share, which is based on actual allowed base period costs on Worksheet 1. A review of the Worksheet 1 data from 2011 and 2012 bid

submissions for all MA carriers shows that EGWP base period allowed claims were 7%-9% higher while risk scores were approximately 4% lower as compared to individual plans.[24] Such differences between plan bids and risk scores are directionally consistent with those noted by CMS in its observations of 2016 bids. Similarly, for Humana's bids from 2014 to 2016, while the magnitude varied from year to year, base period data on Worksheet 1 consistently reflected allowed claims that were higher and risk scores that were lower for EGWP plans than for Individual plans.

We also recommend further analysis by CMS of actual cost and risk score differences between EGWP and Individual MA populations, using Worksheet 1 of historical plan bids. This analysis could then be used to derive B2B ratios that would better align with EGWP costs. CMS has a significant volume of previous bid filings to aid in this analysis. Additionally, to facilitate such analysis on a prospective basis, given the waiving of the bidding requirement for EGWPs, annual reporting by MAOs of EGWP experience may be beneficial. We recommend that any analysis of EGWP costs and risk scores should be delineated by product type and geography to identify if the current EGWP funding methodology needs to be revised to account for these differences.

Regarding the buy-down of Part B premiums, we respectfully disagree that rebate amounts are not identifiable under the current payment methodology that waives the plan bidding requirements. In fact, the rebate amount is defined on page 26 of the Advance Notice. Humana proposes that CMS allow the buy-down of Part B premiums, and follow appropriate steps to track the amount of Part C rebate applied to the Part B premium amount. These steps include the following: 1) publish the EGWP revenue components, including rebate, instead of the combined capitation rate; 2) modify the PBP document to incorporate input of the amount of rebate to be used in buying down the Part B premium; and 3) incorporate a check into the process to ensure that the amount entered into the PBP is no greater than the published rebate amount. We believe this proposed process will ensure that rebates are adequate to fund the buy-down benefit.

<u>Attachment II Section I. ESRD Risk Adjustment Model for CY 2019</u>

The current ESRD model was implemented in 2012. CMS proposes to recalibrate the ESRD model for 2019 using 2014 diagnoses to predict 2015 expenditures. CMS believes that because the 21st Century Cures Act allows all Medicare beneficiaries with ESRD to enroll in MA plans beginning in 2021, plan sponsors may experience an increase in the MA ESRD population. CMS further believes that this justifies updating the ESRD model in advance of that transition.

[24] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/DataFiles.html

Comments: Humana does not support updating the ESRD model at this time. We believe that 2014 and 2015 were anomalous years in the ESRD space. Indeed, as MedPAC has noted, per capita Medicare ESRD spending decreased by 1.2% from 2014 to 2015 due to a statutory update of 0% in 2015 and a decline in the number of dialysis treatments per beneficiary of about 0.8%.[25] Both of these factors are unusual, and in the most recent ESRD payment rule, CMS estimates a net payment rate change of +0.5% on average.[26] Therefore, we believe basing the ESRD model on 2015 costs will result in underpayment relative to the current ESRD cost structure.

Attachment II Section K. Medicare Advantage Coding Pattern Adjustment

For 2019, CMS proposes to update the MA coding adjustment factor to the statutory minimum of 5.90 percent. In addition, CMS seeks comments on three alternative methodologies to inform their final decision regarding the factor for Payment Year 2019.

Comments: We support the CMS proposal to update the MA coding adjustment factor to the statutory minimum for Payment Year 2019. We do not support adjusting the methodology in use to one of the three alternatives that are proposed in the Advance Notice by linkage to previous documents. We provide further comments on the three methodologies below.

For all three methodologies linked to, we do not believe CMS has met the standards for the Advance Notice as set forth in the Social Security Act "to proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement" and providing "an explanation of the assumptions and changes in methodology used in such announcement."[27] In this current Advance Notice, CMS provides no detail on how such methodologies would actually be implemented in the current context. For example, with respect to the methodology described in the Payment Year 2010 Advance Notice and Rate Announcement, the 2019 Advance Notice does not include any details about what cohort years would be used to determine the adjustment amount. This is a critical assumption used in determining the payment methodology. Moreover, in the case of the MedPAC proposal CMS has not made clear if they are literally considering a "cut-and-paste" of the MedPAC view or if this is a concept to be discussed. Either way, MedPAC's proposals contain multiple parts, including a prohibition on diagnoses from health risk assessments. It is unclear if CMS is proposing all or parts of what MedPAC is discussing in the linked document.

In the methodology proposed in the Payment Year 2016 Advance Notice and Rate Announcement, CMS would: 1) estimate the risk of MA-enrolled beneficiaries relative to the risk of beneficiaries in FFS under the AAPCC model; 2) calculate the ratio of MA-to-FFS risk using the CMS-HCC risk adjustment model; and then 3) calculate the MA coding

[25] MedPAC, "Report to Congress: Medicare Payment Policy," March 2017
[26] 82 *Federal Register* 50791
[27] Section 1853(b)(2) and (3) of the Social Security Act

adjustment factor using the difference between these two calculated ratios. CMS states that under its proposed methodology, "payments to MA plans in the aggregate would be no greater than the level of payment that would have been made if CMS was still using the variables in the adjusted average per capita cost (AAPCC) payment system that was in effect prior to 2000."[28]

Although it is not clear how the proposed model would be implemented, it seems that the AAPCC component of CMS's proposal is designed to create an overall financial ceiling on the level and extent of risk adjusted payments made to MA plans. This is based on a perception by CMS that MA enrollees are, on average, likely to have better health risk profiles than demographically similar FFS beneficiaries. **Before implementing a new adjustment that increases reliance on demographic indicators, Humana recommends that CMS study the evidential root causes leading to improved health outcomes among MA enrollees.**

Relevant Statutory Authority

The MA statute provides that CMS shall adjust payments to MA plans for "risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status . . . so as to ensure actuarial equivalence."[29] The statute further requires that, in adjusting for health status, CMS "ensure that such adjustment reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences."[30] The statute required CMS to establish an appropriate adjustment (the "coding intensity factor") for payment years 2008, 2009, and 2010.[31] For payment years 2014 and thereafter, the statute requires CMS to implement coding adjustments not less than certain percentage increases over the 2010 coding intensity factor.[32]

Congress Mandated That CMS Reduce Reliance on AAPCC Risk Adjustment Model Due to Concerns About Inaccurate Prediction of Health Care Costs

CMS has previously acknowledged that the AAPCC risk adjustment model is an inaccurate measure of MA Program costs, stating that "if those who enroll in risk plans are not a representative mix of Medicare beneficiaries (after the risk adjustment factors are considered), HCFA payments based on the AAPCC may not be a particularly accurate estimate of what FFS reimbursements would have been for this group. This potential

[28] Social Security Act, § 1853(a)(1)(C)(iii).
[29] Social Security Act, § 1853(a)(1)(C)(i).
[30] Id. at § 1853(a)(1)(C)(ii).
[31] CMS used its discretion to impose coding intensity adjustments in 2011, 2012 and 2013.
[32] Id. The statute provides that "such adjustment shall be applied to risk scores until the Secretary implements risk adjustment using Medicare Advantage diagnostic, cost, and use data."

problem exists even if the AAPCC methodology forecasts average costs for those in the FFS sector perfectly."[33]

These concerns formed the basis for Congress' mandate, effective in 2000, that CMS develop a new risk adjustment model that takes into account both health status and demographic characteristics. That model guaranteed MA plans sufficient premiums to cover the cost risks assumed by enrolling beneficiaries in poorer health when compared to an average beneficiary. It was designed to allow MA plans to achieve actuarial equivalence in the cost of benefits offered to Medicare beneficiaries with adverse selection considerations removed from the overall equation. As noted in a 2004 report commissioned by CMS:

> "CMS' adaptation of the DCG/HCC model makes substantially more accurate predictions of medical costs for M+C enrollees than has previously been possible. . . . The model has evolved over two decades of research, with careful attention to clinical credibility, real-world incentives and feasibility tradeoffs. . . . The use of a single modeling framework—the CMS-HCC model—provides unity and organization to the subgroup models with the unique features specific to certain types of beneficiaries."[34]

The CMS proposal appears to suggest that the AAPCC methodology more accurately captures the relative risk between MA and FFS than does the CMS-HCC model, and that any differences in the MA to FFS risk scores using the two methodologies must reflect coding pattern differences. This proposition runs counter to the fact that the CMS-HCC model is more accurate and more predictive, and that it – rather than the ratio under the AAPCC model – more accurately reflects relative risk between the two populations.[35]

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[33] Brown, et al., Does Managed Care Work for Medicare? An Evaluation of the Medicare Risk Program for HMOs, conducted under HCFA contract number 500-88-0006 (Dec. 1993) at 4 (emphasis added); see also Gregory C. Pope, et al., Evaluation of the CMS-HCC Risk Adjustment Model, conducted under CMS contract number HHSM-500-2005-00029I (March 2011), pp. 6-7 (the "Pope Report") (stating that "[t]he AAPCC payment methodology explained only about 1 percent of the individual variation in expenditures for Medicare beneficiaries and, for beneficiaries with similar demographic profiles, did not pay more for sicker people.")

[34] Gregory C. Pope, et al., Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model, funding under CMS contract numbers 500-95-048 and 500-00-0030, 25 HEALTH CARE FINANCING REVIEW 140 (Summer 2004).

[35] In describing the benefits of the CMS-HCC model, the Pope Report noted that "[o]ne of the CMS-HCC model's strengths is its facility to be modified for improvements. CMS updates the software annually to account for changes in ICD-9-CM diagnosis codes. It recalibrates the model regularly on more recent diagnosis and expenditure data. Additionally, the CMS-HCC model underwent a major clinical revision in 2009 to adjust for changes in disease patterns, treatment methods, and coding practices, as well as compositional changes within the Medicare population. These modifications have again increased the CMS-HCC model's explanatory power, raising it to 11 percent for the [current] version of the model . . . and . . . 12.5 percent for the [2012 PACE] version of the model."

CMS Proposal Relies on an Assumption That the Current Risk Adjustment Model is Not Accurately Compensating MA Plans Based on Enrollee Health Risk

CMS stated in the 2016 Advance Notice that "the health status of MA enrollees is no worse, and more likely is better, than the health status of FFS beneficiaries of similar age, gender, Medicaid, and institutional status," as evidenced in part by MA enrollees' lower mortality rates and lower utilization of high cost drugs than their FFS counterparts. CMS treats this evidence about the current health outcomes of MA enrollees, however, as indicative of MA enrollees' underlying health risk, stating that "[g]iven the likelihood that MA enrollees are, on average, at similar (or better) risk than demographically similar FFS beneficiaries, we are considering an alternative approach to calculating the coding pattern adjustment for 2017 or future years."[36] **This view of Medicare health outcomes data is potentially flawed in two critical ways:**

1. **It confuses better health outcomes with reduced health status risks and presumes that better health outcomes among MA enrollees are the result of MA enrollees' inherent health status rather than MA enrollees' improved health status resulting from the appropriate medical management programs offered by MA plans; and**

2. **It arbitrarily ignores a key principle underlying health status risk adjustment in the MA program—to set prospective reimbursement rates based on expected cost risks assumed by MA plans so as to provide MA plans with the revenue necessary to allow for improved medical care management as compared to the FFS Program.**

The current CMS risk adjustment framework compensates MA plans based on the underlying health risks of enrollees, which provides a more accurate basis for predicting MA plans' expected costs than the AAPCC model.[37] The health outcomes data cited by CMS may demonstrate that MA plans are managing the health risks of enrollees better than the FFS Program, resulting in better health outcomes. We respectfully request that CMS seek additional information about the underlying reasons for the improved health outcomes cited in these studies prior to modifying the coding adjustment factor. For instance, as illustrated in the chart below, a recent study found that on average MA plans performed better than traditional FFS Medicare on a number of critical HEDIS measures. MA plans spend considerable effort and resources driving quality results. Indeed, an analysis of the CMS Medical Loss Ratio public use file indicates that MA plans, in aggregate, had over $2.67 billion in improving health care quality expenses in CY2014 alone.[38] Notably, that figure does not count bonus payments from value-based arrangements. Collectively, these efforts drive positive clinical outcomes that have little

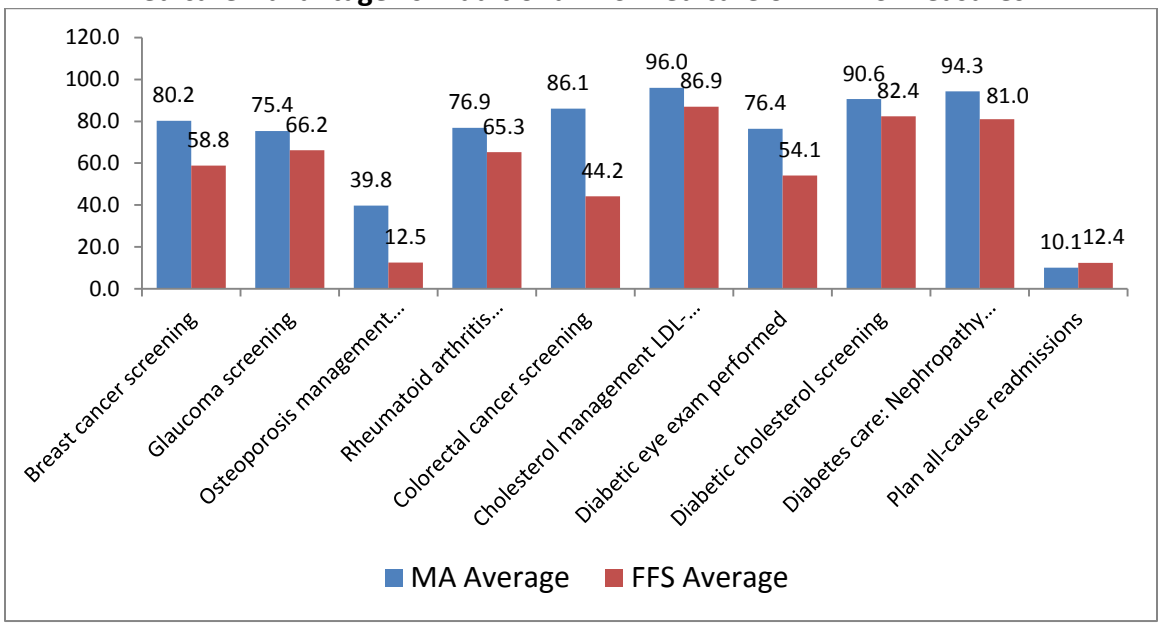
[36] Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter

[37] Under the CMS-HCC model, a comparison of the levels of data accuracy in the MA and FFS Programs remains a necessary element for assuring appropriate payments and actuarial equivalence.

[38] Part C and Part D MLR data: Public Use File for CY 2014, available online at https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/MedicalLossRatio.html

to do with risk selection or demographics, but do have a significant impact on health care costs.

Medicare Advantage vs Traditional FFS Medicare on HEDIS Measures[39]



The MA program was designed to deliver more integrated higher quality care. It would be counterintuitive for CMS to impose a ceiling on the aggregate amount of risk adjustment payments based on an imprecise weighting of demographics that fails to properly consider the impact of medical management. In doing so, the proposed methodology may result in underpayments to MA plans, with the prospect of higher Medicare costs for MA enrollees who return to the FFS Program.

The methodology discussed in MedPAC's March 2017 Report to Congress consists of the following three parts:

1. develop a risk adjustment model that uses two years of FFS and MA diagnostic data;

2. exclude diagnoses that are only documented on health risk assessments from either FFS or MA; and then

3. apply a coding adjustment that fully and equitably accounts for the remaining difference in coding between FFS Medicare and MA plans.

First, as already noted above regarding the three proposals in general, we do not believe CMS has the authority to implement methodological changes of this nature without

[39] Adapted from Timbie, Justin W., et al. "Medicare Advantage and Fee-for-Service Performance on Clinical Quality and Patient Experience Measures: Comparisons from Three Large States." Health Services Research 52.6 (2017): 2038-2060.

more fully describing the methodological approach and impact in the Advance Notice. Second, CMS has already stated in a stakeholder call regarding Part I of the 2019 Advance Notice that it is not planning to implement a risk adjustment model for 2019 that uses two years of diagnostic data.[40]

Third, requiring a subsequent encounter to confirm diagnoses that are only documented on health risk assessments is inconsistent with the design of the risk adjustment model. CMS requires that all diagnosis codes submitted for risk adjustment purposes must be documented in the medical record and must be the result of a face-to-face visit. Visits for the purpose of risk assessments may meet these requirements, and provided they do, there is no basis for excluding them from risk adjustment calculations.

The risk adjustment model is designed to use current year diagnosis information to predict cost in the following year. The model recognizes that the predicted costs associated with treating members with certain diagnoses may not manifest at the time of diagnosis but at some future date. Medicare Advantage Organizations incur liability associated with conditions diagnosed during risk assessments in the same manner they would for conditions diagnosed in other services, including visits to the home or to a provider's office. Therefore, it is inconsistent with the design of the risk adjustment model that diagnoses resulting from risk assessments subsequently unconfirmed by a diagnosis submission provided at a medical facility that same year should be withheld from the following years' payment.

In addition, the MA program incentivizes Medicare Advantage Organizations to ensure their members receive effective treatment for their health conditions in order to avoid incurring greater costs in the future. Requiring a subsequent encounter to confirm a diagnosis conflicts with policies that would ensure that care delivered is necessary and that avoidable cost in the MA program is reduced.

Lastly, requiring a subsequent encounter to confirm a diagnosis presupposes that a diagnosis that is not supported by a subsequent encounter equates to payment error, which under the RADV payment error calculation methodology, requires a comparison to unsupported diagnoses in the FFS data that underlies the risk adjustment model.

Attachment II Section I. Normalization Factors

The preliminary 2019 normalization factor for the CMS-HCC model used in payment years 2017 and 2018 is 1.041, and for proposed "Payment Condition Count" model it is 1.038. Additionally, CMS is proposing to maintain the Payment Year 2018 "linear slope" methodology to project the 2019 normalization factors for all models.

[40] January 16, 2018, CMS stakeholder call on the Advance Notice of Methodological Changes for CY 2019 for the MA CMS-HCC Risk Adjustment Model.

Comments: We thank CMS for proposing separate normalization factors for the CMS-HCC and "Payment Condition Count" models. However, as stated in our comments last year, we believe that deriving a growth rate from a linear model and then compounding that growth rate is inappropriate for several reasons. First, the growth rate used from a linear model should be applied in a linear fashion. If an exponential growth rate is to be used, it should be derived from an exponential model. Second, it is unclear why risk scores are expected to grow in a compound manner. Additionally, we believe that the higher rates of FFS risk score growth observed in 2016 and 2017 as compared to prior years may not continue into the projected year given historical experience, and therefore, the choice of data years used in the calculation will cause the normalization factor to be overstated.

We are concerned that the proposed approach of compounding an annual growth rate derived from a linear model is inappropriate. The correct approach for deriving a compound growth rate would be to solve $(1+r)^n$ for r, where r is the value that minimizes the sum over the n years of squared differences between the actual value and value predicted by the equation. One plus the resulting r would then be compounded for the number of years between the denominator year and the prediction year. We believe a linear model is more appropriate, as there is no reason why risk scores should be expected to grow in a compound manner, but rather than use the linear model to derive a compound growth rate, the linear model should be used directly to predict the 2019 FFS risk score.

As CMS has stated in the Advance Notice, beginning with 2013, the baby boomers aging into Medicare resulted in FFS risk scores increasing at a slower rate than in previous years. However, in 2016, the average FFS risk score increased at the fastest rate ever observed, and the increase in 2017 was only the fourth highest.[41] **To date, CMS has not provided additional detail regarding the anomalous 2016 data point.** CMS has proposed instead to continue the same methodology that was in place for 2018, which would only partially mitigate the impact of this data point on the normalization factor by reverting to the method in place prior to the 2015 bid year of using a linear model, using 5 years rather than 4 years of data. **We recommend that CMS further mitigate the impact of this data point by using 7 years of data rather than 5 when applying their proposed methodology.** The effect of using 7 years of data rather than 5 would be to lessen the impact that the 2016 data point would have on the normalization factor. Applying CMS's methodology through the 7 data points for 2011-2017 would produce a predicted 2019 risk score of 1.032 under the current CMS-HCC model and 1.028 under the Payment Condition Count model.

[41] Based on the current CMS-HCC model risk scores published in this year's Advance Notice, and compared also to the 2014 CMS-HCC model scores going back to 2008 as documented in rate notices from 2014 through 2016.

Attachment II. Section N. Encounter Data as a Diagnosis Source for 2019

For payment year 2019, CMS is proposing to blend risk scores calculated using the Encounter Data System (EDS) risk adjustment model by adding 25% of the risk score calculated with diagnoses from encounter data and FFS with 75% of the risk score calculated with diagnoses from the Risk Adjustment Payment System (RAPS) and FFS.

Comments: Humana appreciates the ongoing collaboration with CMS to make improvements to the encounter data system and process. Through this collaboration and in previous comment letters, we have provided details regarding the various issues and challenges we have experienced. Additionally, several industry reports, including those from Avalere, Milliman, and the Wakely Consulting Group have expressed concerns with the encounter data system and/or encounter data policy and administrative decisions (e.g., the filtering logic).[42] Independent of industry, the Government Accountability Office (GAO) published a study concluding that CMS had not developed requirements for data completeness and accuracy nor performed statistical analyses to detect certain data validity issues and the HHS Office of Inspector General (HHS-OIG) found that even after corrective work by CMS, 5 percent of the encounter data records in their review contained a potential error.[43] Moreover, MedPAC staff has noted that there have been "data and implementation challenges" with the Encounter Data System.[44]

We do not believe the original intent of the encounter data system was to specifically reduce aggregate MA payments. Indeed, in 2015 CMS responding to concerns over the encounter data filtration logic stated, that the "policy being implemented through this filtering logic is the one that CMS has already established (e.g., which service types and physician specialties are allowable sources of diagnoses) and the filtering logic will not change the rules regarding risk adjustment allowable diagnoses."[45] Finally, in the CY2017 Rate Notice, CMS stated noted, that because the encounter data system accepts diagnoses obtained through chart review, MAOs will be able to submit the same diagnoses that they have been submitting into the RAPS. Given that the encounter data system does not change the definition of acceptable diagnoses or limit their submission, CMS anticipates that the risk scores calculated using encounter data will reflect the same coding

[42] Avalere, "RAPS-EDS Collaboration Research Project," January 2017; Milliman, "Medicare Advantage's transition from RAPS to EDS risk scores: 2017 impact," February 2018 http://us.milliman.com/insight/2018/Medicare-Advantages-transition-from-RAPS-to-EDS-risk-scores-2017-impact/;and Wakely Consulting Group, "Impact of EDS on MA Risk Scores," September 2016.

[43] GAO, MEDICARE ADVANTAGE: Limited Progress Made to Validate Encounter Data Used to Ensure Proper Payments GAO-17-223: Published: Jan 17, 2017. Publicly Released: Jan 19, 2017. Available online at http://www.gao.gov/products/GAO-17-223; and HHS OIG, "Medicare Advantage Encounter Data Show Promise for Program Oversight, But Improvements Are Needed," available online at https://oig.hhs.gov/oei/reports/oei-03-15-00060.pdf.

[44] See deck MedPAC, "Using Encounter Data for risk adjustment in Medicare Advantage," April 7, 2016.

[45] CMS, "Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 6, 2015

trend as those calculated with RAPS-based diagnoses. CMS will monitor the impact of using encounter data-based diagnoses on risk scores and risk score trends."[46]

However, the President's Fiscal Year 2019 Budget specifically states that the proposed transition to encounter data is designed to reduce MA plan payments. The HHS Budget in Brief estimates that the transition to encounter data will reduce plan payments by approximately $11.1 billion over 10 years.[47] Humana does not support a purposeful reduction to MA payments via encounter data.

Moving forward, Humana supports the following approach to the encounter data issue:

1) **We respectively request that CMS develop and publish an operational plan and strategy, complete with a schedule for remediating these issues, metrics to assess performance, and details around the CMS and MA organizational resources deemed necessary to achieve the desired improvements;**

2) **To address the reduction in risk scores, Humana supports the concept of an equitable industry-wide adjuster that accurately pays each sponsor for their risk. We further urge that CMS either maintain that adjuster or return to a 100 percent RAPS risk score weighting until the encounter data issues can be fully resolved; and**

3) **We recommend that CMS consider an industry-wide adjustment to previous payment years to correct for any inappropriate underpayment that has resulted from the EDS issues. Humana acknowledges that this may be considered a retrospective change in payment method not supported by the law. However, CMS does have the discretion to reopen payment years to correct for administrative errors. If an adjustment is not feasible, we recommend that CMS reopen payment years to correct for EDS errors once the system issues have been resolved.**

Attachment III. Section B. Encounter Data as a Diagnosis Source for 2019

For payment year 2019, CMS is proposing to blend risk scores calculated using the Rx-HCC risk adjustment model by adding 25% of the risk score calculated with diagnoses from encounter data and FFS with 75% of the risk score calculated with diagnoses from the Risk Adjustment Payment System (RAPS) and FFS.

[46] CMS, "Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 4, 2016

[47] HHS, Fiscal Year 2018 HHS Budget in Brief, p. 68. https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf

Comments: Humana strongly opposes increasing the encounter data weighting for risk scores given the concerns outlined above regarding the current validity and accuracy of encounter data.

Attachment III. Section C. Part D Risk Sharing

CMS has found that risk sharing amounts continue to vary significantly in aggregate from year-to-year and among Part D sponsors in any given year. Therefore, CMS does not believe it is appropriate to adjust the parameters at this time, and will apply no changes to the current threshold risk percentages for contract year 2019.

Comments: Humana believes that the analytic approach CMS has taken with respect to Part D risk sharing is appropriate. We support the proposal to apply no changes to the current threshold risk percentages for contract year 2019.

Attachment VI. Draft CY 2018 Call Letter

Enhancement to the 2019 Star Ratings and Future Measurement Concepts

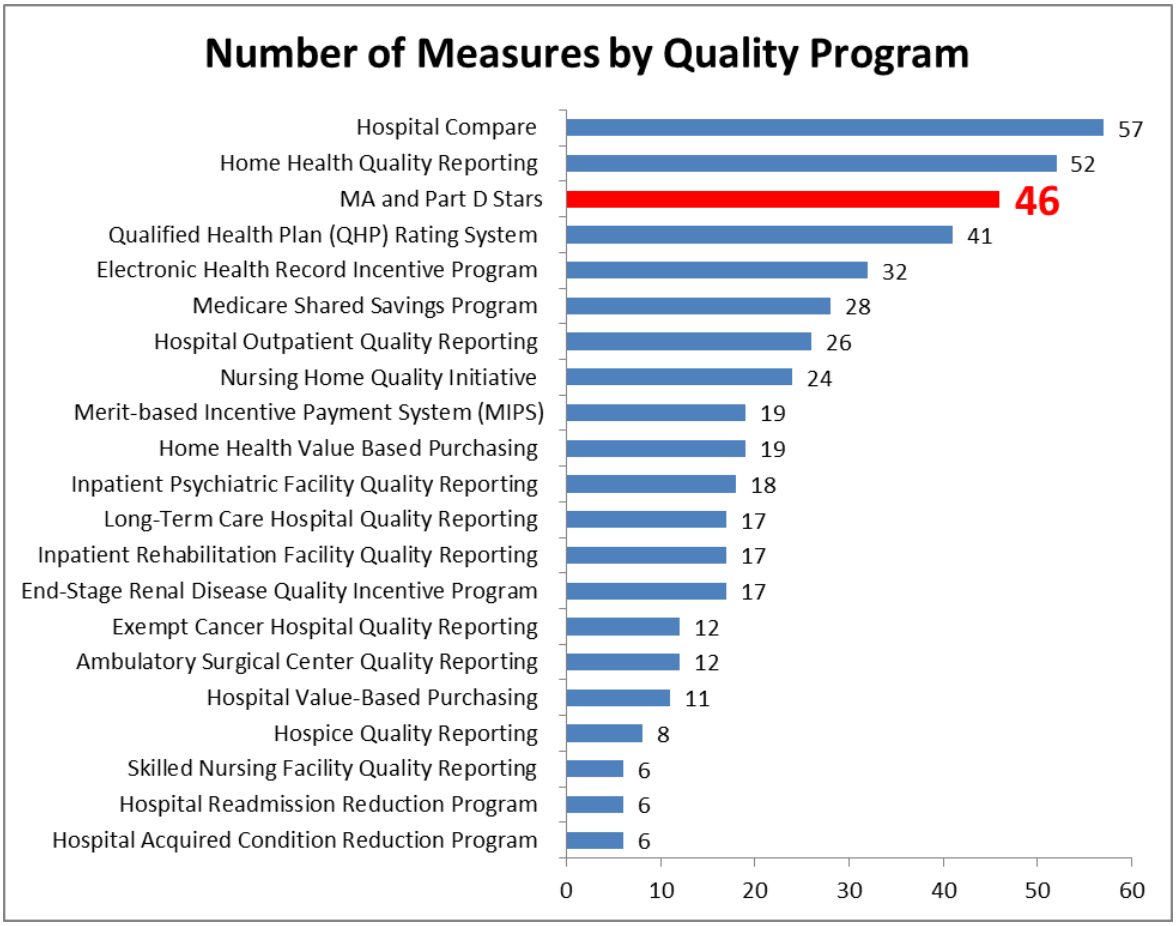
CMS publishes the Part C and D Star Ratings each year to measure the quality of and reflect the experiences of beneficiaries in Medicare Advantage (MA) and Prescription Drug Plans (PDPs or Part D plans), assist beneficiaries in finding the best plan, and determine MA Quality Bonus Payments. Further, the Star Ratings support the efforts of CMS to improve the level of accountability for the care provided by physicians, hospitals, and other providers.

Comments: Humana supports the evolution and development of an effective quality program that ensures the best health outcomes for all Medicare Advantage enrollees. To support this objective, Humana recommends reducing the frequency of changes to the program, in order to allow health plans and physicians to effectively dedicate resources, implement changes, and observe outcomes.

To this end, CMS's recent proposal to adopt a formal rulemaking process for future Star Ratings changes will lead to more robust stakeholder feedback versus the existing Advance Rate Notice and Call Letter process (which is targeted primarily at MAOs versus the entire stakeholder community). We also hope that by more effectively engaging the provider community and other key stakeholders in the identification and implementation of Star Ratings measures, CMS will begin to more closely align quality measurement across the fee-for-service and MA programs – alleviating burden on health care providers.

In the interim, as part of the CMS Administrator's Meaningful Measure initiative, we strongly encourage CMS to identify opportunities to more closely align quality measurement across the MA and other CMS programs, including traditionally FFS Medicare.

Humana also supports the Administrator's "Patients over Paperwork" initiative.[48] Most Stars measures create additional burden on providers and beneficiaries, either through the measurement process or activities to increase performance. As illustrated in the chart below MA and Part D Stars have more measures than many CMS quality systems.[49] Accordingly, we urge CMS to work toward efficient Stars measurement.



<u>New Measures for 2019 Star Ratings – Statin Use in Persons with Diabetes (SUPD)</u>

CMS proposes to add the SUPD measure to the 2019 Star Ratings (based on 2017 data) with a weight of 1 for the first year. In subsequent years, CMS proposes a weight of 3 as an intermediate outcome measure, as prescription fills are a proxy for patients taking their prescribed medications, and adherence is necessary to reach clinical/therapeutic goals. Additionally, CMS, for the 2017 measurement year, is proposing to expand its data sources for identifying all Part D enrollees with ESRD for exclusion from the measures to include ICD-10-CM codes found in both Part A & B claims and Risk Adjustment Processing System (RAPS) RxHCCs to use along with the EDB ESRD indicator that is currently used.

[48] What is Patients over Paperwork? See https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/PoPDecember2017Newsletter.pdf

[49] Sources: https://cmit.cms.gov/CMIT_public/ListMeasures, https://qpp.cms.gov/mips/overview, and https://data.medicare.gov/data/hospital-compare

Comments: The U.S. Preventive Services Task Force (USPSTF) finds from their literature review, that "adults 76 years and older were not included in any of the randomized trials of statin use for the primary prevention of [cardiovascular disease] CVD. Thus, understanding of the potential benefits of initiating statin use for primary prevention in this age group is limited. Evidence on the potential harms of statin use for the primary prevention of CVD events in adults 76 years and older is also very limited. Observational evidence suggests there may be an association between very low cholesterol levels and an increased risk of mortality with advanced age, after adjusting for other risk factors."[50] While the American College of Cardiology/American Heart Association's treatment guidelines are not as conservative as USPSTF, they do caution that "the use of statin therapy should be individualized in persons >75 years of age" taking into consideration adverse effects, drug–drug interactions, and patient preferences."[51] The current Medication Adherence for Cholesterol (Statins) measure did not account well for the cautions presented in these guidelines. It appears that the proposed statin measures are an improvement in that they do not apply to members over the age of 75. However, it is not clear the measure allows for the exclusion of people with statin intolerance from the denominator. Randomized trials, when compared to a placebo, have shown intolerance rates as low as 1.5%[52] to as high as 25-30%[53] in observational studies. We urge CMS, to allow for the exclusion of members with a noted statin intolerance.

Approximately 35-40% of members eligible for the Statin Use in Patients with Cardiovascular Disease (SPC) measure are also eligible for the SUPD measure. Humana suggests that CMS evaluate creating one combination measure based upon the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults to adequately and comprehensively measure all members who should initiate statin therapy without significant duplication between measures.

While we concur with CMS's statement that "prescription fills are a proxy for patients taking their prescribed medications, and adherence is necessary to reach clinical/therapeutic goals," the SUPD measure solely measures the initiation of therapy (i.e. a single fill of the medication) and not continuous adherence. Given the large

[50] U.S. Preventive Services Task Force Final Recommendation Statement Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication, available online at https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/statin-use-in-adults-preventive-medication1

[51] Goff, David C., et al. "2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines." Journal of the American College of Cardiology 63.25 Part B (2014): 2935-2959.

[52] Stroes ES, Thompson PD, Corsini A, et al. Statin-associated muscle symptoms: impact on statin therapy-European Atherosclerosis Society Consensus Panel Statement on Assessment, Etiology and Management. *Eur Heart J* 2015;36:1012–22

[53] Molokhia M, McKeigue P, Curcin V, et al. Statin induced myopathy and myalgia: time trend analysis and comparison of risk associated with statin class from 1991–2006. PLoS ONE 2008;3:e2522.

number of measures already included in the Stars Rating program, we question whether two statin measures are warranted, particularly given the CMS Administrator's agency-wide initiative to eliminate redundant and unnecessary quality measures.

If CMS elects to move forward with the SUPD measure, we recommend that CMS not triple weight SUPD as an intermediate outcomes measure. Instead, we recommend that CMS review the classification of this measure as adherence based and consider it to be similar to the Rheumatoid Arthritis Management and Osteoporosis Management HEDIS measures, which are classified as 1x weighted process measures, as the focus is on initiation of therapy, not chronic utilization.

Additionally, we appreciate the proposed change to exclude ICD-10 codes, found in Part A & B claims and the RAPS system, but would suggest CMS also evaluate the inclusion of other codes that may indicate a contraindication or significant caution to therapy, such as rhabdomyolysis.

New Measures for 2019 Star Ratings – Statin Therapy for Patients with Cardiovascular Disease

CMS proposes to include the Statin Therapy for Patients with Cardiovascular Disease measure in the 2019 Star Ratings as a process measure with a weight of 1, as it is based on medical records review if medications were prescribed.

Comments: As discussed above, approximately 35-40% of members eligible for SPC are also eligible for the SUPD measure. Humana recommends that CMS evaluate creating one combination measure based upon the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults to adequately and comprehensively measure all members who should initiate statin therapy based upon the guidelines without significant duplication between measures.

Changes to Measures – MPF Price Accuracy (Part D)

CMS proposes enhancements to the MPF Price Accuracy measure to better measure the reliability of a contract's MPF advertised prices. The modified measure would be a display measure for 2020 and 2021. CMS is also considering whether to add the measure to the 2022 Star Ratings. Pending such a change, CMS proposes to continue to include the current MPF measure in the Star Ratings using the same methodology used for the BY19, until the modified measure is incorporated.

Humana Comment: We concur with CMS's proposal to publish the modified measure as a display measure for 2020 and 2021 before potentially adding it to the 2022 Star Ratings. We also support the agency's proposal to continue to include the current MPF measure in the Star Ratings using the same methodology as the 2018 Star Ratings.

Changes to Measures – Members Choosing to Leave the Plan (Part C & D)

CMS proposes to expand exclusions for the Members Choosing to Leave the Plan measure to include Plan Benefit Package (PBP) service area reductions that result in the unavailability of PBPs that the enrollee is eligible to move to within the contract.

> **Comments: We support the CMS proposal to expand the list of exclusions and further recommend that the expanded list include "members who switch plans within the same Parent Organization." A member choosing to switch plans, but remain within the same Parent Organization, is not a definitive reflection of contract-level dissatisfaction. Further, the inclusion of this variable in the measure does not accurately depict the overall quality of the plan and does not provide prospective enrollees useful information for making an informed plan selection.**

Removal of Measures from Star Ratings – Beneficiary Access and Performance Problems (BAPP) (Part C & D)

CMS proposes to retire the current Beneficiary Access and Performance Problems (BAPP) measure from the 2019 Star Ratings. The measure will be modified to only include Compliance Activity Module data. The revised measure would be included on the display page for 2019 Star Ratings.

> **Comments: Humana urges CMS to permanently retire the BAPP measure from Stars. With the notable exception of Nursing Home Compare, CMS quality measurement systems generally are not based on compliance or audit results. For example, the words "compliance" and "audit" appear nowhere in the CMS Quality Measure Development Plan for the Quality Payment Program.[54] We do not believe it is appropriate to have a compliance-focused measure in a performance system that is designed specifically to focus on clinical quality and the perspective of the beneficiary. We also believe that the BAPP measure is a form of "double-dipping" that overlaps other measures. An examination of the 2018 Part C and D Star Ratings, CMS public use file shows significant contract level correlations (presented in the table below) between the BAPP and other measures impacted by compliance issues, such as, C32: Plan Makes Timely Decisions about Appeals.**

[54] CMS Quality Measure Development Plan: Supporting the Transition to the Quality Payment Program 2017 Annual Report

Contract level correlations between the Beneficiary Access and Performance Problems and other Stars Measures[55]

	C30: Beneficiary Access and Performance Problems
C08: Special Needs Plan (SNP) Care Management	-.227**
C23: Getting Appointments and Care Quickly	.250**
C29: Members Choosing to Leave the Plan	.192**
C32: Plan Makes Timely Decisions about Appeals	.264**

**Correlation is significant at the 0.01 level

Temporary Removal of Measure from Star Ratings – Reducing the Risk of Falling (Part C)
NCQA is making two changes to the Reducing the Risk of Falling measure within the HOS survey. As a result of these changes, CMS proposes to revise the underlying questions as part of the 2018 survey. This change will result in no data being available for 2019 Star Ratings. CMS proposes to add the measure to the 2020 display page and include it in the 2021 Star Ratings.

Comments: We recommend that the display period for HOS measures be extended to account for the current overlap between data reporting and data collection for the next cycle. This would allow for plans to fully evaluate the impact of the changes and provide feedback to CMS on any unintended consequences.

Proposed Scaled Reductions for Appeals IRE Data Completeness Issues
CMS proposes statistical criteria to reduce a contract's Star Rating for data that are not complete or lack integrity using TMP data or audit results. CMS's proposed scaled reduction methodology would be a three-stage process using the TMP data and audit results for making their determination. Any reduction would be applied to the contract's associated appeals measure-level Star Ratings.

Comments: We support CMS's proposal to use a scaled reduction approach in Star Ratings for appeal measures in both Part C and D, in lieu of a standard reduction to 1 Star.

2019 Star Ratings Program and the Categorical Adjustment Index (CAI)
CMS proposes to will continue to use their current methodology for CAI adjustment and has updated the list of measures used to calculate the CAI values. The list includes six Part C measures and two Part D measures based on the 2016 measurement year results. Additionally, CMS is considering risk-adjusting the medication adherence measure and implementing stratified reporting for four HEDIS measures.

[55] Analysis based on the 2018 Part C and D Star Ratings CMS public use file.

Comments: We support CMS's continued efforts to improve the CAI.

2019 CAI Values

CMS proposes updated CAI values that modify both the LIS/DE groupings and the final applied CAI values. The Disability Quintile groupings would remain relatively unchanged.

Comments: We support CMS's continued efforts to improve the CAI.

Disaster Implications – Identification of Affected Contracts

CMS proposes several criteria for determine contracts directly affected by natural disasters. Affected contracts would be eligible for potentially two adjustments to their scores for most measures. The proposal would limit adjustments to appropriately targeted areas to ensure plans impacted by the disasters are receiving necessary support. Additionally, CMS proposes that all contracts solely operating in Puerto Rico would be treated as affected contracts, without further analysis, as a result of the extraordinary damage and beneficiary disruption caused by Hurricane Maria.

Comments: We fully support CMS's proposal to prevent adverse plan rating impacts for enrollees affected by disaster. Further, we request CMS publish, on CMS.gov, a list of MA contracts that meet the 25% affected enrollee threshold prior to the plan preview periods for a given rating year. We recommend that the list include the following information: measure type (CAHPS, HOS, HEDIS, Other), contract, percentage, numerator, and denominator.

Taking an unknown, but potentially significant number of contracts out of the pool used for cut point calculations, could introduce unexpected volatility. For this reason, we recommend that CMS explore adopting a stability provision to avoid extreme shifts from year-to-year, if warranted, during the Plan Preview period.

New 2019 Display Measure – Plan Makes Timely Decisions about Appeals (Part C)

CMS proposes a new display measure that would include cases dismissed by the IRE into the Plan Makes Timely Decisions about Appeals calculation. Currently all cases dismissed and withdrawn by the IRE are excluded from the calculation. The modified measure would be on the 2019 and 2020 display page before potentially returning to the 2021 Star Ratings. The current measure would then be retired.

Comments: We recommend that the Plan Makes Timely Decisions about Appeals (Part C) measure be weighted by membership to ensure plans of all sizes are measured equally. This objective can be achieved by calculating the measure similarly to the Part D Auto-Forwards measure. In this example, the calculation would be the number of untimely cases sent to IRE (including dismissals) per 10,000 members.

Changes to Existing Display Measures – Hospitalizations for Potentially Preventable Complications (Part C)

NCQA is considering updating the measure specifications to include hospital stays that are considered "observation stays" to improve completeness of the measure. As a result, CMS proposes to retain this measure as a 2019 display page measure, and potentially move it to a Star measure, with a weight of 1, for the 2022 Star Ratings. Beyond the 2022 Star Ratings, the measure would be triple weighted as an outcomes measure.

Comments: We support the adoption of the Hospitalizations for Potentially Preventable Complications Star measure, and concur with the agency's proposal to keep the measure on display for 2019 due to the NCQA's significant technical specification changes. Additionally, from a clinical perspective, we welcome NCQA's changes as beneficiaries could incur actual hospital stays that are considered observation stays due to a failure to prevent condition complications.

Changes to Existing Display Measures – High Risk Medication (Part D)

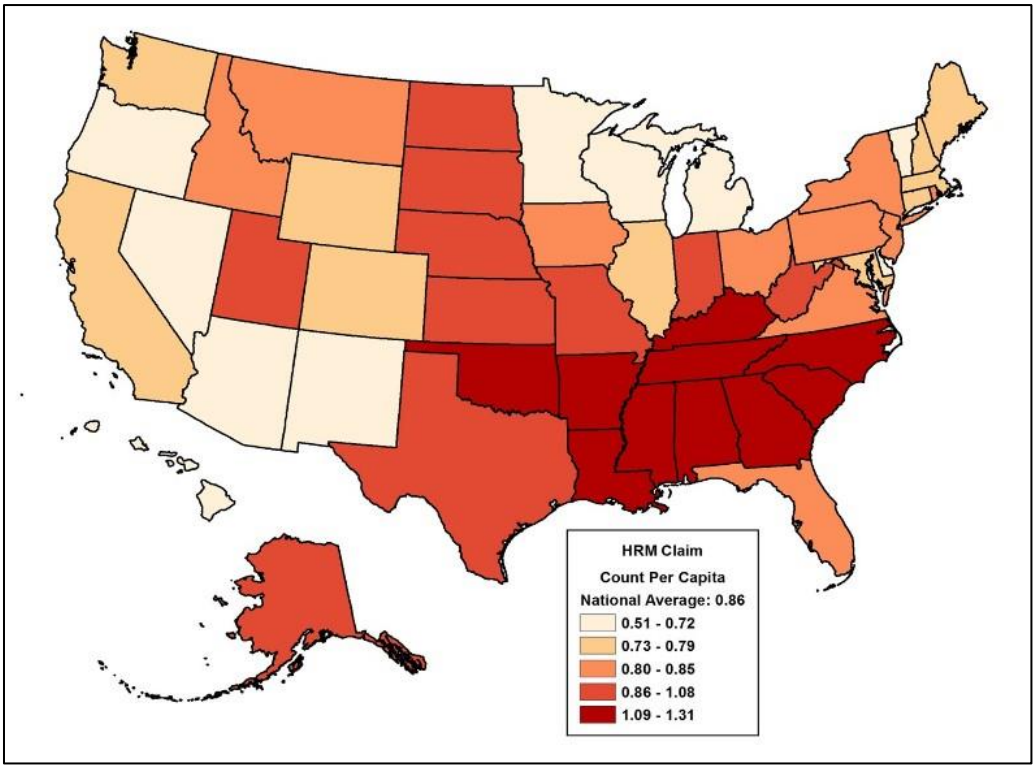
CMS proposes to keep the High Risk Medication (HRM) measure on the display page for 2019 (based on 2017 data). CMS also proposes to adopt a specification change made by the PQA to measure specifications for the numerator (beneficiaries with at least two fills of the same HRM drug on different dates of service) for the 2019 display measure.

Comments: We support CMS's proposal to keep the HRM measure on display. However, as illustrated in the figure below, CMS analysis of the data show unexplained geographic variations in per capita HRM fills that cannot be attributed to the plan.[56] The map shows the average number of high risk medications prescribed to elderly beneficiaries. The national average for prescribing high risk medications was 0.86 claims per elderly beneficiary in CY2014. The lowest rates of high risk medication prescribing are found in some Western states, Midwestern states, such as Minnesota, Wisconsin, and Michigan, as well as states in New England. States with the highest rates of high risk medication prescribing, which range from 1.09 to 1.31 claims per elderly beneficiary, are concentrated in the South. Similarly, the Dartmouth Atlas found considerable variation across regions, noting a "threefold difference between the percent of patients treated with a high-risk medication in Rochester, Minnesota (14.0%) and the percent treated in Alexandria, Louisiana (43.0%).[57] If CMS intends to incorporate the HRM measure into future Stars Ratings, we strongly encourage CMS to work with measure developers and Part D plans to explore ways to mitigate the impact of geographic variations in HRM prescribing, so that all MA contracts are on a level playing field.

[56] CMS Updated prescriber-level Medicare data available online at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-18.html

[57] Jeffrey C. Munson, et al, "The Dartmouth Atlas of Medicare Prescription Drug Use," October 15, 2013.

High Risk Medication (HRM) Fills per Capita among Elderly Beneficiaries, 2014



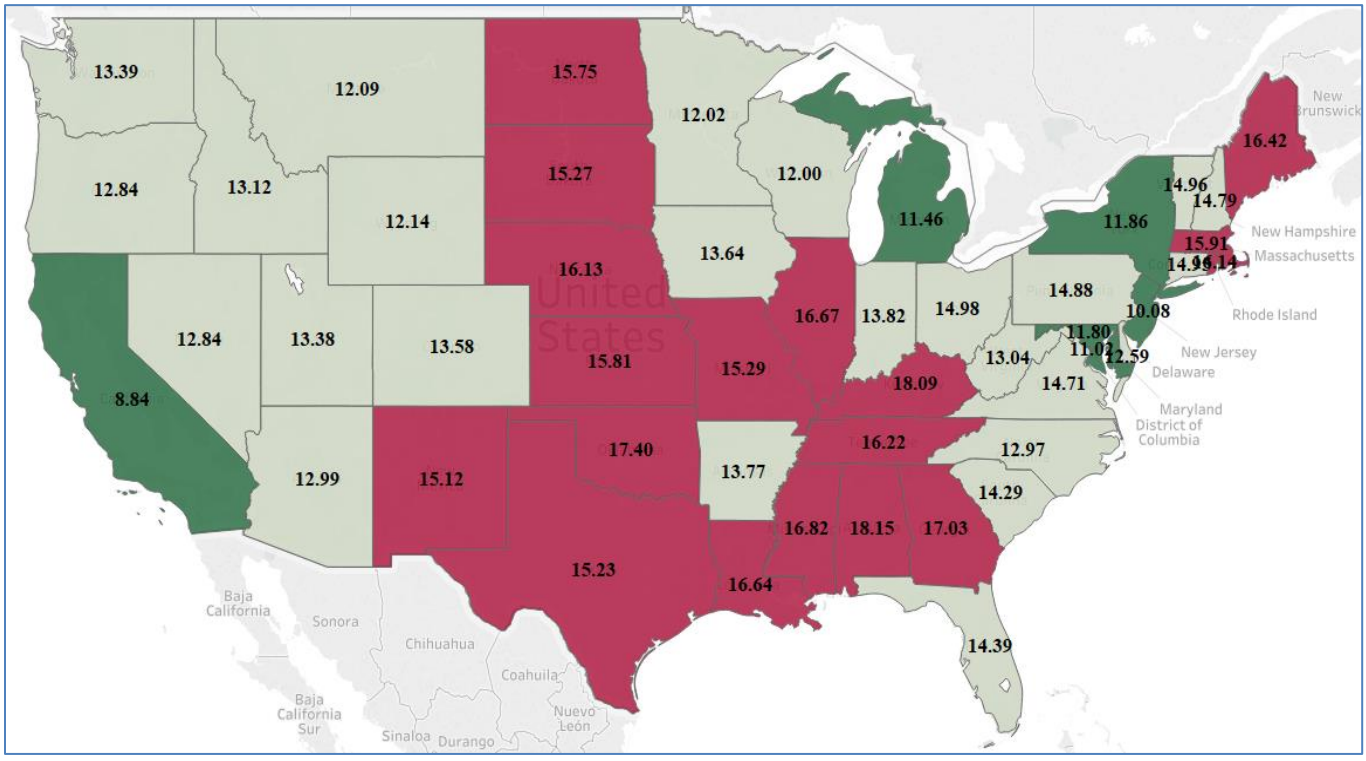
Changes to Existing Display Measures – Antipsychotic Use in Persons with Dementia (APD)
CMS proposes to display the rates for the two population breakouts on the 2019 display page (in addition to the overall APD rate currently displayed). CMS will assess adding the APD measure to the Star Ratings in the future, which would be proposed through rulemaking.)

> **Comments: As CMS and the HHS Office of Inspector General have noted, antipsychotics are likely overprescribed and off indication, especially in long-term care settings.[58] Humana supports policies that would reduce unnecessary utilization of antipsychotics. However, we urge CMS when developing Stars measures on this issue, to consider the system-level factors impacting use that are largely out of the control of Part D sponsors. First, antipsychotics are within the protected classes, thus generally limiting the use of prior authorization by the Part D sponsor. Second, and perhaps more important, there are noted geographic variations in antipsychotic use. For example, one study found the weighted average propensity of prescribers to adopt new antipsychotics varied four-fold across hospital referral regions (HRRs).[59]**

[58] CMS, "Antipsychotic Use in Part D Enrollees with Dementia," November 16, 2015; CMS, "Analysis of Medicare Part D Enrollees Who Use Antidepressant or Antipsychotic Medications," March 5, 2015; and HHS OIG, "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents Report (OEI-07-08-00150)," May 2011
[59] Donohue, Julie M., et al. "Regional variation in physician adoption of antipsychotics: Impact on US Medicare expenditures." The journal of mental health policy and economics 19.2 (2016): 69.

At the state level, an examination of the CMS 2015 Part D Prescriber public use file yields a nearly 12.8% spread in the percentage of Part D enrollees utilizing an antipsychotic from the lowest utilizing state (Hawaii) and the highest (DC). This level of variation in antipsychotic utilization between states still exists after adjusting for differences in the state prevalence rates of schizophrenia and other psychotic disorders using data from Medicare Chronic Conditions Dashboard. This suggests that there could be substantive geographic variations in prescription practices. There is also geographic variation in antipsychotic use in skilled nursing facilities (SNFs). The aforementioned OIG work specifically called out practices in SNFs as a root cause of antipsychotic overprescribing. As illustrated in the map below, the most recent CMS Nursing Home Compare data show an over 11% spread in the facility level median percentage of residents using antipsychotics by State.[60] We believe system level factors, such as differences in State regulation of nursing facility minimum staffing ratios, drive these differences and are generally out of the control of the plan sponsor. Accordingly, we urge CMS to develop an appropriate geographic adjustment for this measure.

Median Facility Level Percentage of Nursing Home Residents Using Antipsychotics



*Note: Organized by low risk (**dark green**), middle risk (light green), and high risk (**red**).*

[60] Analysis of Nursing Home Compare data last updated on 1/24/2018, available online at https://data.medicare.gov/data/nursing-home-compare. Medians were calculated due to the skewed distribution of facility level percentages of antipsychotic use, both nationally and at the State level.

Changes to Existing Display Measures – Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D)

PQA will be revising measures in 2018 based upon new CMS guidelines. After the PQA measures are updated, CMS will reassess the measures for possible inclusion in Star Ratings.

Comments: Humana supports PQA's mission to collaboratively promote appropriate medication use.

Changes to Existing Display Measures – Timely Effectuation of Appeals (Part D)

CMS proposes to modify the Time Effectuation of Appeals measure to be all appeals received by the IRE during a defined timeframe rather than all data applicable as of the date the report is generated by the IRE. Additionally, CMS proposes to exclude the results of appeals that occur beyond Level 2.

Comments: We support the proposed modification of this measure, which we believe will allow plans to better monitor and validate the final results.

Potential Changes to Existing Measures – Controlling High Blood Pressure (Part C)

NCQA is evaluating potential updates to the Controlling High Blood Pressure measure for HEDIS 2019 based on new guidelines from the American College of Cardiology and the American Heart Association. Additionally, NCQA is exploring modifications to the denominator.

Comments: We strongly support NCQA's efforts to identify opportunities to leverage administrative data to demonstrate compliance and reduce administrative burden.

Potential Changes to Existing Measures – Plan All-Cause Readmissions (Part C)

NCQA is exploring several revisions to the Plan All-Cause Readmissions measure, including:

- inclusion of observation stays in the denominator and numerator;
- adding death in measurement year as a possible factor in the risk adjustment model;
- revising the measure denominator to be the overall population as opposed to index hospital admits; and
- possible stratification of PCR re-admits to identify the percentage of discharges that result in an unplanned readmit during or after a SNF stay

In addition, CMS is proposing to combine rates for ages 18+ rather than 65+ for the revised PCR. This revised measure would be part of the display page for 2019 and 2020 before moving to the 2021 Star Ratings with a weight of 1 the first year and a weight of 3 thereafter.

Comments: We request additional context from CMS given our concerns regarding the impact of revising the measure denominator to be equal to the overall plan population instead of index hospital admissions. The proposed change in the denominator appears to be predicated on the uncertain assumption that there will be a consistent ratio of members to stays. We request the opportunity to further study

the potential impacts of this proposal and provide feedback on any unintentional consequences prior to implementation.

Potential Changes to Existing Measures – Cross-Cutting Exclusions for Advanced Illness (Part C)
NCQA is evaluating the clinical appropriateness and feasibility of excluding individuals with advanced illness from selected HEDIS measures due to the measures not being clinically appropriate for certain individuals with advanced illness and potentially overlooking quality issues specific to these patients. NCQA is assessing the need for having exclusions for selected HEDIS measures for patients with advanced illness where providing certain treatments and services may not be appropriate. NCQA is exploring which specific illnesses and healthcare utilization may warrant exclusion and to which measures the exclusion should be applied. If approved, updates to HEDIS measures, for any additional exclusion, would be incorporated in HEDIS 2019.

Comments: We agree that specific illnesses and health care utilization may warrant excluding certain beneficiaries from the following measures: Rheumatoid Arthritis Management; Osteoporosis Management in Women who had a Fracture; Controlling Blood Pressure; Comprehensive Diabetes Care; Breast Cancer Screening; Colorectal Cancer Screening; and Statin Therapy for Patients with Cardiovascular Disease.

There is growing body of literature and research indicating that older beneficiaries should not be subjected to certain preventive screenings. For example, The U.S. Preventive Services Task Force is examining strategies to better stratify their recommendations older adults.[61] Researchers are also beginning to question whether some preventive screening may actually harm rather than help older beneficiaries given the difficulty in detecting certain diseases in patients with multiple comorbidities. According to growing chorus of medical specialties, including the American College of Surgeons, the Society of General Internal Medicine, and the American Cancer Society, some of these tests and screenings are resulting in invasive and possibly unnecessary follow-up testing and treatment.[62]

[61] *Reconsidering the Approach to Prevention Recommendations for Older Adults*. U.S. Preventive Services Task Force. February 2014. https://www.uspreventiveservicestaskforce.org/Page/Name/reconsidering-the-approach-to-prevention-recommendations-for-older-adults

[62] *Doing More Harm Than Good? Epidemic of Screening Burdens Nation's Older Patients*. Kaiser Health News. December 20, 2017. https://khn.org/news/doing-more-harm-than-good-epidemic-of-screening-burdens-nations-older-patients/; http://www.choosingwisely.org/clinician-lists/american-college-surgeons-colorectal-cancer-screening-tests/. http://www.choosingwisely.org/clinician-lists/society-general-internal-medicine-cancer-screening-in-adults-with-life-expectancy-less-than-10-years/; https://www.cancer.org/healthy/find-cancer-early/cancer-screening-guidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer.html; https://www.healthaffairs.org/action/showDoPubSecure?doi=10.1377%2Fhblog20171117.664355&format=full

Potential Changes to Existing Measures – Center for Medicare and Medicaid Innovation Model Tests

The Part D Enhanced Medication Therapy Management Model tests whether providing Part D sponsors with additional payment incentives and regulatory flexibilities will engender enhancements in the MTM program, leading to improved therapeutic outcomes, while reducing net Medicare expenditures. CMS has waived the MTM requirements for Part D plans participating in the Model. Part D sponsors with plans participating in this model must establish MTM programs in compliance with current requirements and reporting data for the remaining plans under each Part D contract. The MTM Program CMR Completion Rates will be calculated using available plan-reported data from the remaining plans under a Part D contract. CMS plans to analyze if their approach significantly advantages or disadvantages Enhanced MTM model participants and evaluate potential adjustments as necessary, including the establishment of different cut points for model participants or to case-mix adjust scores for the purpose of determining cut points.

> **Comments: As an active participant in the Enhanced MTM model (EMTM) with CMMI, Humana recommends that CMS publish the results of their analysis and offer MAOs the opportunity to comment prior to making any decisions that could impact Star Ratings.** The EMTM gives participating plans the opportunity to define targeting strategies for EMTM PDP members. Such targeting provides these plans the flexibility to offer EMTM PDP members comprehensive medication review (CMR) services in accordance with their targeting practices. We are concerned that a plan's targeting strategy could impact PDP CMR completion and ultimately impact the plan's Star rating.

Potential New Measures for 2020 and Beyond – Transitions of Care (Part C)

CMS proposes to include the Transitions of Care measure with the following four indicators on the 2020 display measure for possible inclusion in the 2022 Star Ratings.

- Notification of Inpatient Admission: Documentation of primary care practitioner notification of inpatient admission on the day of admission or the following day
- Receipt of Discharge Information: Documentation of primary care practitioner receipt of specific discharge information on the day of discharge or the following day
- Patient Engagement After Inpatient Discharge: Documentation of patient engagement (e.g., office visits, visits to the home, or telehealth) provided by primary care practitioner within 30 days after discharge
- Medication Reconciliation Post-Discharge (which is currently a HEDIS measure): Documentation of medication reconciliation within 30 days of discharge

> **Comments: We support efforts to enhance the physician-patient relationship, and concur with the important quality concept that this measure seeks to address.**

Potential New Measures for 2020 and Beyond – Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions (Part C)

CMS is considering adopting a new HEDIS measure assessing follow-up care provided after an emergency department visit for patients with multiple chronic conditions. NCQA is evaluating

what timeframe (e.g., 7, 14, or 30 days post-emergency department visit) and what types of follow-up (e.g., face-to-face office visits, telephone or web interactions, or visits to the home) are appropriate. CMS plans to propose to include this measure on the 2020 display page for possible inclusion in the 2022 Star Ratings.

> **Comment: Based on our analysis of a full month sample of Emergency Department (ED) claims from the 2017 measurement year, we have concerns around the timely receipt of these claims, allowing ample time to impact the measure. In our analysis, less than 30% of claims were received within seven days of the ED visit and less than 5% of the claims were received in the first four days. Given this lag in claims submission by hospital emergency departments, health plans may not receive data in a timely manner to ensure that patients receive a follow-up with their PCP within seven days. Additionally, it is not uncommon for this population to be diagnosed with multiple chronic conditions, but seek care in the emergency department for reasons other than their chronic conditions (e.g. falls or UTI). As a result, we recommend that CMS not adopt this HEDIS measure for Stars.**

Potential New Measures for 2020 and Beyond – Care Coordination Measures (Part C)
CMS is working to expand efforts to better evaluate a plan's success at effective care coordination. The agency has identified potential new care coordination measures and is currently testing them for possible future implementation. CMS will provide more details at a later date.

> **Comments: We encourage CMS to provide plans with an opportunity to review any proposals and provide substantive feedback well in advance of any future implementation.**

Potential New Measures for 2020 and Beyond – Opioid Overuse (Part C)
For HEDIS 2018, NCQA is collecting data on Use of Opioids at High Doses and Use of Opioids from Multiple Providers which are adapted from the PQA's opioid measures. CMS requests feedback on the value of including these Part C measures on the display page, given the similar Part D measures that constitute data for Patient Safety reports back to plans and which may also be reported on the display page.

For HEDIS 2019, NCQA will be testing a new measure concept that addresses members who were previously naïve to opioids who become long-term or "chronic" users. NCQA wants to properly define "opioid naïve and chronic use." NCQA is also considering testing a second measure concept that addresses the concurrent prescription of opioids and central nervous system (CNS) depressants. The goal, for both concepts, is to understand feasibility and utility of reporting the measure at the health plan level, in addition to identifying populations that warrant exclusion from the measure.

Since similar measures are being or have been developed as Part D measures, CMS is interested in feedback not only on the measure concepts, but also whether and how MA contracts have a

unique role and responsibility, in contrast to stand-alone prescription drug plans, regarding opioid use, misuse, abuse and/or dependency, none of which would be captured by Part D measures. CMS would also be interested in feedback on the value of these measure concepts and how to weigh that value in contrast to any burden from measurement in this area.

> **Comments:** Humana is committed to reducing inappropriate utilization of opioids. As part of these efforts, we have implemented a comprehensive prescription opioid utilization program that consists of data analytics, surveillance, and outreach initiatives to detect and address opioid-related waste, fraud, and abuse. **We applaud CMS for seeking opportunities to leverage the Star Ratings to incent plans to adopt strategies to reduce overutilization of opioids. However, as CMS acknowledges in the draft Call Letter, similar measures are already being used successfully to reduce overutilization in the Part D program, and thus may prove redundant if applied to Part C.**

Potential New Measures for 2020 and Beyond – Assessment of Care for People with Multiple High-Risk Chronic Conditions (Part C)

NCQA is considering a new measure concept that would adapt the current Care for Older Adults measure by expanding the number of indicators and broadening the populations covered by the set of measures. The new measure, Assessment of Care for People with Multiple High-Risk Chronic Conditions, would apply to all Medicare plans and would target the population of people with two or more high-risk chronic conditions. This new measure would assess the percentage of members who had an expanded assessment during the measurement year. The measure concept is currently undergoing testing to assess feasibility, alignment with current practice, and gaps in care. CMS requests feedback about expanding the number of indicators and broadening the product line beyond Medicare SNPs.

> **Comments: We encourage NCQA to ensure that the new measure effectively evaluates the assessment of care without resulting in unnecessary administrative burden for providers and plans.**

Potential New Measures for 2020 and Beyond – Depression Screening and Follow-Up for Adolescents and Adults (Part C)

NCQA has developed a measure assessing the percentage of patients age 12 and older who are screened for depression using a standardized assessment tool, such as the PHQ-9, and if positive, receive appropriate follow-up care within 30 days of the positive screen. This measure is part of NCQA's new effort to collect data using an Electronic Clinical Data System (ECDS). Depending on the results during the first year of implementation, CMS may consider this measure for the display page and Star Ratings in the future.

> **Comments: We support the adoption of the Depression Screening and Follow-Up for Adolescents and Adults measure, as it is clinically appropriate. However, we recommend the completion of a depression screening, with adequate follow up, be conducted at the provider-level rather than health plan level. We are concerned that plans may lack the information necessary to identify all members with depression.**

If health plans are deemed responsible for follow-up, we request that CMS specify how plans will identify members with depression (e.g. claims data, pharmacy data, referral from other clinical service areas or physicians). Additionally, we ask for clarification around the inclusion and exclusion criteria for member in the denominator for this measure.

Potential New Measures for 2020 and Beyond – Unhealthy Alcohol Use Screening and Follow-Up (Part C)

NCQA adapted the provider-level NCQA measure Unhealthy Alcohol Use: Screening & Brief Counseling (NQF 2152) for health plan reporting. A number of health plans have been helping to test and evaluate performance for the adapted measure and to gather information on feasibility of implementation at the health-plan level. This measure is part of NCQA's new effort to collect data using electronic clinical data systems (ECDS). Depending on the results during the first year of implementation, CMS may consider this measure for the display page and Star Ratings in the future.

Comments: As the ECDS methodology matures, Humana supports the exploration of additional measures derived from these data sources. We recommend that the health plan be allowed to act on behalf of a provider to perform an assessment with the member to help coordinate care and support the physician-patient relationship.

Potential New Measures for 2020 and Beyond – Readmissions from Post-Acute Care (Part C)

NCQA is pursuing opportunities to measure acute facility readmissions during or following a skilled nursing facility (SNF) stay for Medicare beneficiaries. NCQA is exploring the development of a new measure or the potential adaption of the Plan All-Cause Readmissions (PCR) measure to evaluate acute facility readmissions among Medicare beneficiaries during or after a SNF stay. If approved, the new measure or revisions to the current PCR measure would be included in HEDIS 2019. CMS requests feedback on the feasibility, utility, and burden of such a modification/stratification or new measure.

Comments: We acknowledge the clinical relevancy of the proposed measure, but request that NCQA publish their justification for including readmissions during a SNF stay. Based on our experience, MA plans have minimal ability to impact these types of readmissions. Inpatient admissions during a SNF stay are most directly attributable to the SNF – not plans.

Potential New Measures for 2020 and Beyond – Adult Immunization Measure (Part C)

For HEDIS 2018, NCQA added the Pneumococcal Vaccination Coverage for Older Adults measure to the ECDS reporting domain. Measures in the HEDIS ECDS domain are calculated using electronic data from administrative claims, electronic medical records, case management systems and registries. For HEDIS 2019, NCQA will build off the pneumococcal measure and evaluate the relevance, scientific soundness, and feasibility of a composite measure for HEDIS that assesses the receipt of routine adult vaccinations.

Comments: Electronic data sources will eventually provide a valuable source for accurate vaccination reporting. To-date, there are approximately 60+ different immunization registries (some states have multiple) and each registry has different requirements. To decrease this complexity, we recommend that CMS work with the Centers for Disease Control and Prevention to explore establishing a centralized national registry prior to implementing this measure for Star Ratings.

Potential New Measures for 2020 and Beyond – Polypharmacy Measures (Part D)

CMS proposes to begin reporting the Polypharmacy: Use of Multiple Anticholinergic Medications in Older Adults measure in the Patient Safety reports for the 2018 measurement year. CMS plans to add the measure to the display page for 2021 and 2022. CMS also intends to consider proposing this measure via rulemaking for the 2023 Star Ratings.

CMS proposes to begin reporting the Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS) measure in the Patient Safety reports for the 2018 measurement year. CMS plans to add the measure to the display page for 2021 and 2022. CMS will consider proposing this measure through rulemaking for the 2023 Star Ratings.

Comments: We support CMS addressing the issue of polypharmacy. We also view polypharmacy measures as preferable to the existing HRM measure discussed previously in our comments. However, as CMS moves forward, we recommend that the agency continue to evaluate Part D plans' ability to impact these measures. We also encourage CMS to explore additional opportunities within FFS to influence prescriber behavior and reduce inappropriate polypharmacy by aligning these efforts with the Merit-based Incentive Payment System (MIPS).

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

CMS is proposing to display an icon or other type of notice on Plan Finder for sponsoring organizations that have received a Civil Money Penalty (CMP). Currently, this information is available to the public via the CMS website.

Comments: **While Humana appreciates CMS's aim of transparency, we do not believe this Plan Finder CMP icon, as proposed, will be a useful tool for beneficiaries to assist in their selection of a Medicare plan.** The CMS audit process of MA plans and PDPs is enormously complex, and we are concerned that the addition of an icon will cause confusion for beneficiaries if it is included without careful consideration and explanation of the information it provides. Additionally, CMS does not audit every MA plan and PDP annually and thus, not all plans have the potential to receive a CMP each year. This proposal does not address how CMS will ensure a level playing field with plans that are not audited, as it would be unclear whether the absence of the CMP icon is due to an audited plan not receiving a CMP or because the plan was not audited at all. As CMS notes, CMP information is already made public and Humana recommends that CMS not finalize this Plan Finder CMP icon until these concerns are addressed.

New Medicare Card Project (formerly the Social Security Number Removal Initiative, SSNRI)
CMS reminds plan sponsors that, beginning in April 2018, the current Social Security Number based Health Insurance Claim number (HICN) will be replaced with a new Medicare number, the Medicare Beneficiary Identifier (MBI). MBIs will be assigned to all Medicare beneficiaries and new Medicare cards will be mailed to beneficiaries starting in April 2018. During the April 2018 to December 31, 2019 transition period, Medicare plans can use either the HICN or the MBI to exchange data with CMS.

Comments: Humana appreciates the information CMS has provided and the actions the agency has taken to help plan sponsors prepare for the transition to MBIs. However, we continue to have concerns and questions that have yet to be addressed by CMS. First, due to the volume and the significance of the Medicare ID as a primary identifier of a beneficiary, it will take plans time to update membership data with the transition from the HICN to the MBI. Because CMS will not be able to accept MBIs prior to April 1, 2018, plans cannot begin processing files early, as transactions sent to CMS with MBIs will be rejected. As such, plans must hold outbound transactions for a period of time prior to April 1 or hold Transaction Reply Report (TRR) transactions after April 1 to make system updates and prevent rejections and access to care issues for beneficiaries. **Humana suggests that CMS allow for a relaxation of compliance timelines specific to enrollment, disenrollment, maintenance transactions, and corresponding processes (i.e. letters, ID cards, system updates, etc.) in the weeks prior to and after April 1 to allow plans adequate time to make updates.**

It is our understanding that CMS intends to begin using the MBI of the Monthly Membership Report (MMR) beginning in April 2018, but does not intend to use the MBI on the Model Output Report (MOR) until January 1, 2020, after the end of the transition period. **These two files are complementary and as such, *Humana recommends that CMS begin using the MBI on the MOR, as well as on the MMR, beginning in April 2018.***

Employer groups have received conflicting responses from CMS regarding the impact of the MBI transition on their plans and regarding what is expected of them for this process. ***We recommend that CMS publish additional educational materials and FAQs specific to the transition process for employer groups.*** **Additionally, we suggest that CMS establish a work group specifically tailored to issues for the employer group community that will bring together stakeholders to address their unique needs.**

CMS has provided plan sponsors with its New Medicare Card Mailing Strategy, but detailed information is only available for actions to be taken through June 2018. **Humana requests that CMS update the Mailing Strategy to provide additional, longer-term details so plan sponsors can better prepare call centers to receive and answer beneficiary questions regarding the new ID cards.** Additionally, during the annual election period, Medicare beneficiaries often receive new plan ID cards. **Humana**

recommends that CMS coordinate the delivery of new Medicare ID cards containing the MBI with plan sponsors so as to avoid beneficiary confusion during this period.

Humana also suggests that CMS provide flexibility allowing plan sponsors to submit either HICNs or MBIs during the audit process, particularly when the audit period is prior to 2020. Plans may not have completely transitioned from using the HICN to using MBIs prior to 2020 and while some plans may have the ability to provide historical, point-in-time data, others may only be able to provide the current beneficiary IDs. Being too prescriptive with regards to which beneficiary ID must be submitted by a plan during an audit could be problematic for some plan sponsors and given that the objective can be achieved using either ID number, CMS should allow this flexibility within the audit process.

Meaningful Difference (Substantially Duplicative Plan Offerings)

CMS is currently reviewing public comments on the agency's recent proposal to eliminate meaningful difference requirements for MA plans.[63] CMS will provide instructions in the final rule and the CY 2019 Final Call Letter or a HPMS memorandum regarding the meaningful difference requirements for CY 2019.

Comments: As noted in the comments that Humana submitted in response to the proposed rule (CMS-4182-P), Humana supports the agency's proposal to eliminate the meaningful difference requirement related to the MA program. Humana commends CMS's desire to encourage innovation, its recognition that beneficiaries do not want their plan choices limited, and its assessment of the limitations of the existing meaningful difference evaluation. **We believe that eliminating the meaningful difference requirement will allow MA plan sponsors to implement new benefit designs more closely aligned with current and future beneficiary needs rather than actuarial calculations.**

Total Beneficiary Cost (TBC)

CMS proposes to change in TBC limit from $34 in CY2018 to $36 in CY2019. The agency further proposes to eliminate the current TBC evaluation and invites suggestions on alternative approaches to determine excessive benefit decreases from one plan year to the next.

Comments: Within the current TBC methodology, Humana believes that increasing the TBC limit to $36 is reasonable. The higher limit offers MAOs more flexibility in designing CY2019 plans. However, Humana encourages CMS to eliminate the current TBC evaluation.

When designing benefits and premiums, Humana's goal is to provide year-to-year stability for our members, because we believe this positively affects the member's experience and

[63] CMS, Medicare Program; 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 (CMS-4182-P).

satisfaction with the Medicare Advantage program. The competitive environment also drives MA plans to maintain benefits and premiums that members find attractive and valuable, which effectively dampens TBC increases from year to year. These considerations influence plan design much more than the TBC evaluation, as evidenced by the vast majority of our plans passing the TBC test by large margins. However, we must still evaluate the TBC test repeatedly prior to initial submission and again during Rebate Reallocation to ensure compliance for 100% of our plans.

The recent Medicare Advantage and Part D proposed rule (CMS-4182-P) proposed eliminating the current Meaningful Difference Requirement for CY2019 bids. For the past several years, both the Meaningful Difference and TBC requirements have used the same CMS Out of Pocket Cost (OOPC) Model to evaluate the expected cost sharing payable under each MA plan. The proposed rule cited a number of issues regarding newer plan designs and concerns that,

> "…CMS believes that it is challenging to apply the current standardized meaningful difference evaluation (which is applied consistently to all plans) in a manner that accommodates and evaluates important considerations objectively. CMS is concerned that the current evaluation may create unintended consequences related to innovative benefit designs."[64]

CMS further states that,

> "In order to capture differences in provider network, more tailored benefit and cost sharing designs, or other innovations, the evaluation process would have to use more varied and complex assumptions to identify plans that are not meaningfully different from one another. CMS believes that such an evaluation could result in more complicated and potentially confusing benefit designs to achieve differences between plans. This process may require greater administrative resources for MA organizations and CMS, while not producing results that are useful to beneficiaries."[65]

While the proposed rule focuses on differences between multiple plans in the same contract year, these same concerns are applicable to year-over-year design changes in the same plan.

Part C Cost Sharing Standards

CMS requests comments concerning whether the agency's current interpretation of cost sharing limits is impacting plans' ability to offer more flexible benefit designs that would provide beneficiaries with valuable plan options.

[64] 82 FR 56363.
[65] 82 FR 56364

Comments: Humana believes that cost sharing limits inhibit a plan's ability to offer more flexible benefit designs. However, we also recognize the need to protect beneficiaries from unreasonably high cost sharing and that some form of cost sharing limits is necessary. To this end, we recommend that CMS adopt cost sharing limits that are objectively measurable and meaningful for beneficiaries.

We believe the In-Network Service Category Cost Sharing Requirements (SCCSR) published in the Call Letter in recent years accomplishes these objectives. However, for services where CMS has not established a specific service category cost sharing limit, CMS's "longstanding interpretation of the antidiscrimination provisions that payment of less than 50% of the contracted (or Medicare allowable) rate and use of cost sharing for services that exceeds 50% of the total MA plan financial liability for the benefit discriminates against enrollees who need those services" is unnecessarily complex. A Parent Organization with many plans must calculate and manage many different cost sharing limits across all plans and services. Plans may aggregate claims data in different ways to calculate the average contracted rate for a service. A plan's average financial liability for each service may vary substantially from year to year as utilization patterns or provider contracts change, especially if there is low utilization volume for a service in a plan. Plans may need to apply various credibility principles to the calculated data to ensure cost sharing stability from year to year. The current 50% limit also allows for higher cost sharing for plans with higher contracted rates, which does not appear to protect the beneficiary. Under this interpretation, a copayment amount could be considered discriminatory for some plans, but not others. **For these reasons, we believe that each plan's implementation of the 50% rule may be different, and that can have significant impact on the resulting limits.**

To make the limits more meaningful for beneficiaries, we recommend that CMS adjust the list of services in the SCCSR to include only those services which CMS believes are most meaningful to beneficiaries and would therefore require explicit cost sharing limits. For example, our consumer research has frequently cited Inpatient Hospital Acute, Primary Care Physician, Physician Specialists, and Prescription Drug as the cost sharing categories with the most impact on consumer decisions. For all other services, rather than using the 50% limit, we believe CMS can use the MA Bid Pricing Tool Worksheet 4 calculation of Reduction of A/B Cost Sharing in cells Q78:Q88 to assess whether a plan's cost sharing is discriminatory. Either PMPM or percentage of Allowed Cost limits could be established for any subset of these cells. Such an approach would reflect all provider contracts, geographic variations in costs, and projected utilization patterns. It would also incorporate any designs that adopt MA Uniformity Flexibility features.

Finally, if CMS elects to continue publishing the In-Network Service Category Cost Sharing Requirements in the Call Letter, we suggest that CMS list all limits that MAOs are expected to follow. On Page 179 of the Draft CY2019 Call Letter, CMS describes concerns related to cost sharing that exceeds 50% of the total MA plan financial liability

with cardiac and pulmonary rehabilitation cited as examples with specified limits that are non-discriminatory. If CMS expects MAOs to adhere to these limits and documentation requirements consistent with those cost sharing categories in the SCCSR, we request that the agency include those limits in Table 24 on page 178.

Part C Optional Supplemental Benefits

CMS proposes to continue reviewing non-employer bid submissions to verify enrollees electing optional supplemental benefits are receiving reasonable value. CMS also proposes to continue considering a plan to be non-discriminatory when the total value of all optional supplemental benefits offered to non-employer plans under each contract meets the following thresholds: 1) the enrollment-weighted contract-level projected gain/loss margin, as measured by a percent of premium, is no greater than 15%; and 2) the sum of the enrollment-weighted contract-level projected gain/loss margin and non-benefit expenses is no greater than 30%.

Comments: Humana appreciates the ability to offer optional supplemental benefits (OSB) to enrollees. Humana requests CMS broaden the definition of OSBs to allow for benefits beyond those that are permitted for MSBs. OSB premiums are solely funded by the member, not Medicare dollars, and therefore MAOs should have the flexibility to offer benefits beyond those allowed as mandatory supplemental benefits. Humana's internal research indicates that consumers want to be empowered to enjoy a healthy life, value security and predictability, want to be in control of their lives, and be reassured that they are not a burden to family. Allowing expanded optional benefits such as such as international travel coverage, cosmetic/wellness services, final expense, addresses these needs by supporting financial health and enhancing beneficiaries' quality of life.

Tiered Cost Sharing of Medical Benefits

For CY 2019, CMS does not expect MAOs to submit a proposal summarizing their intent to tier cost sharing of medical benefits prior to bid submission. MAOs are instead expected to simply indicate they are tiering medical benefits and the applicable service categories in Section A-6 of the PBP. MAOs must use minimum/maximum data entry and notes fields to describe tiering in each applicable section of the PBP.

Comments: Humana appreciates the ability to tier cost sharing of medical benefits, which provides beneficiaries access to quality, high performing providers at a lower cost. Humana supports the elimination of the tiered cost sharing proposal submission.

Health Related Supplemental Benefits

An item or service is primarily health related if the primary purpose of the item or service is to prevent, cure, or diminish an illness or injury. CMS has not previously allowed an item or service to be eligible as a supplemental benefit if the primary purpose is daily maintenance. However, medical and health care research has demonstrated the value of certain items and services that can diminish the impact of injuries or health conditions and reduce avoidable

emergency and health care utilization. CMS proposes to expand the scope of the primarily health related supplemental benefit standard by interpreting Section 1852(a)(3) of the Social Security Act more broadly to permit MA plans to offer additional benefits as supplemental benefits.

Comments: Humana applauds CMS's proposal to allow plans to offer enhanced supplemental benefits that can enhance beneficiaries' quality of life and improve health outcomes. Many factors contribute to overall health that cannot be directly linked to medical services or treatments. It is estimated that approximately half of the factors influencing health are attributable to social and environmental differences.[66] Allowing MAOs to expand supplemental benefits will have positive impacts on social and environmental determinants and ensures a holistic approach to enhancing health outcomes for the Medicare population.

For example, Humana urges CMS to consider extending benefit and cost sharing flexibility to supplemental benefits targeted at addressing the social determinants of health (SDOH). The literature clearly demonstrates that health is influenced by more than just medical-specific factors.[67] Indeed, social determinants of health (SDOH), such as food security, housing, transportation, availability of resources, safe communities, and social interaction, among others, also play a role in the overall health of all individuals. The recognition that health is affected by social determinants is increasing, with the Department of Health and Human Services (HHS) including addressing SDOH as one of the four overarching goals of its Healthy People 2020 initiative. The specific initiative goal related to SDOH is to "create social and physical environments that promote good health for all," a goal shared by the World Health Organization, which is also working on addressing this issue across the globe.[68] As such, **we believe that if CMS finalizes this proposal, the agency should immediately issue guidance allowing for benefit designs that will address food insecurity and social isolation.** To be clear, we are asking for updated guidance around defining what is acceptable as a MA supplemental benefit. We are not asking for additional payments.

Humana has been working for many years on addressing the social determinants that are impacting the health of our members and their communities. Humana launched its Bold Goal initiative in 2015, with the objective of improving the health of the

[66] McGinnis JM, 2002

[67] Alley, D. E., Asomugha, C. N., Conway, P. H., & Sanghavi, D. M. (2016). Accountable health communities—addressing social needs through Medicare and Medicaid. *N Engl J Med*, *374*(1), 8-11; Adler, Nancy E., et al. *Addressing Social Determinants of Health and Health Disparities*. Discussion Paper, Vital Directions for Health and Health Care Series. National Academy of Medicine, Washington, DC. https://nam. edu/wp-content/uploads/2016/09/addressing-social-determinantsof-health-and-health-disparities; Braveman, Paula, and Laura Gottlieb. "The social determinants of health: it's time to consider the causes of the causes." *Public Health Reports* 129.1_suppl2 (2014): 19-31; and Meddings, Jennifer, et al. "The impact of disability and social determinants of health on condition-specific readmissions beyond Medicare risk adjustments: A cohort study." *Journal of general internal medicine* 32.1 (2017): 71-80.

[68] See https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health

communities we serve 20 percent by 2020. Through this initiative, Humana partners with local nonprofits, businesses, and governments as well as physicians and other medical providers within their communities to develop innovative programs designed to improve the clinical health outcomes of individuals by addressing social needs. Because of the Bold Goal pursuit, Humana has gained a deeper understanding of the need for addressing SDOH to improve clinical health, has gained experience in implementing programs and partnerships to do this, and has a greater appreciation for the importance of this work.[69] Despite the innovative work in this area by Humana and others, current MA regulations and interpretive guidance stipulate that plan sponsors can only offer narrowly-defined supplemental benefits that are primarily medical-related.

Food insecurity: Food insecurity, defined by the U.S. Department of Agriculture (USDA) as a lack of access to enough nutrient-rich food for a healthy, active life, has been shown to have a detrimental effect on health. A recent study found that food insecure seniors are 65 percent more likely to be diabetic, twice as likely to report fair or poor health, 19 percent more likely to have high blood pressure, 57 percent more likely to have congestive heart failure, 66 percent more likely to have experienced a heart attack, and 2.3 times more likely to suffer from depression.[70] A recent pilot program undertaken by Humana in partnership with Feeding America and Feeding South Florida, administered a food insecurity screening and a health-related quality of life survey to patients at three primary care clinics in south Florida, with those screening positive for food insecurity being provided food resources on site and referred to additional community resources. The program used the Centers for Disease Control-developed Healthy Days measure to examine health-related quality of life and The Hunger Vital Sign™ food insecurity screening tool. Results from the pilot found that food insecure individuals had nearly twice as many physically unhealthy days per month as food secure individuals (13.68 days versus 7.44) as well as more than twice as many mentally unhealthy days per month (12.91 days versus 6.10).[71]

At present, MA plan sponsors can offer meal services to their plan enrollees under particular circumstances and only for a limited period of time within the supplemental benefit regulations. Meals can be provided if the services are needed due to an illness (i.e. certain chronic conditions, or immediately following surgery or an inpatient hospital stay), are consistent with the established medical treatment of an illness, and are offered for a short duration. Currently, regulations prohibit social factors, on their own, from qualifying an MA enrollee for meal services.[72]

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[69] See http://populationhealth.humana.com/wp-content/uploads/2017/03/Humana_BoldGoal_2017_ProgressReport-v2.pdf

[70] Craig Gundersen and James P. Ziliak. The Health Consequences of Senior Hunger in the United States. 2014.

[71] See http://apps.humana.com/marketing/documents.asp?file=3105791

[72] Chapter 4, Medicare Managed Care Manual, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf

Accordingly, we urge CMS to work with plans to design policies allowing plans to address food insecurity through a targeted modification of the Medicare Managed Care Manual Chapter 4, Section 30.3, which contains language limiting the provision of meals to enrollees by MA plans. Specifically, meal services should be allowed as supplemental benefits for any member: 1) who meets the USDA definition of having "very low food security;[73]" 2) who is eligible for the Medicare Diabetes Prevention Program or who is currently diabetic and has issues accessing food that would prevent disease progression; or 3) is eligible for the Supplemental Nutrition Assistance Program (SNAP). For enrollees eligible for SNAP, MA organizations should be able to coordinate and wrap meal services around that benefit to ensure that members have enough nutritious food to last throughout each month. MA plans should also be able to provide meals for a longer duration, such as three to six months rather than the current two to four weeks. CMS should also allow for regulatory flexibility for MA plans to provide non-medical transportation services if transportation is deemed a barrier to accessing healthy food.

Loneliness and social isolation: Loneliness, social isolation, and the availability of community-based resources in support of community living and opportunities for recreational and leisure-time activities can also play an important role in patient health.[74] According to research from the AARP Foundation, 17% of adults age 65 and older are isolated and a recent study found that social isolation and loneliness increase the likelihood of mortality by 29% and 26%, respectively.[75,76] Another study, conducted by researchers from the AARP Public Policy Institute, Stanford University, and Harvard University, found that Medicare spends an estimated $6.7 billion more annually on seniors who have little social contact with others.[77] Research has also shown links between social isolation and increased risk of diabetes and dementia.[78,79]

One of the largest root causes of loneliness and social isolation is challenges with or lack of access to transportation. Seniors without access to transportation and/or who have retired from driving are often unable to participate in community activities and therefore to connect in-person with others. Lack of transportation may also exacerbate

[73] U.S. Department of Agriculture, Economic Research Service, "Food Security Measurement," available at https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/measurement/
[74] HHS, "Healthy People 2020 and Social Determinants of Health," available at https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health
[75] See https://connect2affect.org/
[76] Holt-Lunstad, J., Smith, T. B., Baker, M., Harris, T., & Stephenson, D. (2015). Loneliness and social isolation as risk factors for mortality: A meta-analytic review. Perspectives on Psychological Science, 10, 227-237.
[77] AARP Insight on the Issues: *Medicare Spends More on Socially Isolated Older Adults* (November 2017). https://www.aarp.org/content/dam/aarp/ppi/2017/10/medicare-spends-more-on-socially-isolated-older-adults.pdf
[78] Brinkhues et al. Socially isolated individuals are more prone to have newly diagnosed and prevalent type 2 diabetes mellitus. BMC Public Health (2017) 17:955 DOI 10.1186/s12889-017-4948-6
[79] Wilson RS, Krueger KR, Arnold SE, Schneider JA, Kelly JF, Barnes LL, Tang Y, Bennett DA. Loneliness and Risk of Alzheimer Disease. Arch Gen Psychiatry. 2007;64(2):234–240. doi:10.1001/archpsyc.64.2.234

food insecurity, as vulnerable seniors may not be able to travel to grocery stores with healthier foods, and instead may have to rely on more easily accessible fast food options that are closer to their homes.

The Medicare Managed Care Manual Chapter 4, Section 30.3 states that transportation can be offered to MA enrollees as a supplemental benefit "exclusively to accommodate the enrollee's health care needs: for example, the MA plan may offer a supplemental benefit that provides transportation to enrollees for physician office visits." Further, the manual chapter explicitly states that the transportation "may not be used to transport enrollees for non-health related purposes."[80] Humana encourages CMS to modify the Medicare Managed Care Manual Chapter 4, Section 30.3 requirement for transportation and allow MA plans to provide transportation services as a supplemental benefit. Specifically, transportation should be allowed to be offered to members who are socially isolated to the point where that isolation is a root cause for clinical depression or other behavioral issues.

Medicare Advantage (MA) Segmented Service Area Options

CMS is revising its interpretation of current regulations to allow MA plan segments to vary by supplemental benefits, premium, and cost sharing, consistent with the MA regulatory requirements defining segments at §422.262(c)(2).

Comments: Humana supports the ability to vary supplemental benefits across segments.

Medicare Diabetes Prevention Program (MDPP) Services Clarification

CMS proposes to allow MAOs to offer additional, virtual format MDPP-like services as a supplemental benefit. MAOs cannot provide MDPP services only remotely or in a 100% virtual format, but could provide additional, similar diabetes prevention services in a virtual format under the Remote Access Technology supplemental benefit.

Comments: We encourage CMS to provide MA plans with additional information regarding CMS-approved suppliers for MDPP services. It is our understanding that plans should initially consult a list of providers maintained by the Centers for Disease Control and Prevention (CDC).[81] However, some of providers on the CDC list do not have a Medicare ID. In addition, the CDC list includes several online-only providers, which we assume, based on previous CMS regulations and guidance are not eligible for reimbursement. Furthermore, based on our initial inspection, the CDC list includes several suppliers that limit their services only to their employees. **As a result, we strongly encourage CMS to issue a complete list of CMS-approved, Medicare-eligible MDPP providers.**

[80] Chapter 4 Medicare Managed Care Manual https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf

[81] https://nccd.cdc.gov/DDT_DPRP/Registry.aspx

Expanding the Part D OTC Program

CMS is contemplating allowing additional flexibilities for Part D plan sponsors to offer access to over-the-counter drug products (OTCs) and is soliciting feedback from stakeholders on Part D OTC enhancements that could be considered for future policy. This feedback could include information on how well the current program is working, the deficiencies of the current program, what additional flexibilities would be helpful, and what the impact would be on spending, particularly premiums, as a result.

> **Comments:** As CMS has indicated, Section 1860D-2(e)(2)(A) of the Part D statute prohibits coverage of OTCs except in very limited situations. Current law does not permit the coverage of OTCs to be funded with anything other than administrative plan costs. It is unclear what CMS believes it can do under the existing statutory framework. **Humana recommends that CMS consider issuing a formal Request for Information (RFI) on potential coverage changes to OTC products under Part D to allow for a more robust discussion of options under current law, including the use of demonstration authority.**

Part D Benefit Parameters for Non-Defined Standard Plans

As in prior years, CMS has proposed to set the out-of-pocket cost (OOPC) differential between sponsors' basic and first enhanced plan based on the 50th percentile of the November CY 2018 bid data, run through the updated CY 2018 OOPC MPF model. For 2019, the proposed differential amount is $22. In addition, though CMS has proposed to eliminate OOPC requirements between a plan sponsor's first and second enhanced plans in the "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 (CMS-4182-P), CMS did not provide any guidance in the Call Letter, and stated that additional information would be included in the upcoming Final Rule.

> **Comment:** As noted in our prior comments, **Humana is fully supportive of CMS's proposal to eliminate meaningful difference requirements between EA plans** included in CMS-4182-P**.** Finalizing this proposal will allow sponsors to better design plans around current and future beneficiary needs, as opposed to designing plans to meet actuarial calculations. We strongly encourage CMS to adopt this proposal for the 2019 plan year.
>
> **Furthermore, we ask that CMS finalize this guidance as soon as possible, even before issuing the final rule.** Though Humana appreciates the complexities of making such decisions, the lack of guidance in the Call Letter creates operational challenges for plan sponsors, as they will need to address multiple OOPC scenarios throughout bid planning, until a final decision is published.
>
> In addition, we continue to ask that CMS create a consistent OOPC differential between basic and enhanced plans that does not change from year to year if they do not eliminate the meaningful difference requirements, maintaining the CY 2018 differential

amount, $20, for CY 2019. This would afford sponsors more predictability and reduce unnecessary changes, while still ensuring beneficiaries receive meaningful value.

Benefit Parameters for CY 2019 Threshold Values

CMS proposes to maintain the current brand copayment maximums of $47 for the preferred brand/brand tier and $100 for the non-preferred brand and non-preferred drug tiers.

Comment: Humana recommends that CMS make an inflationary adjustment to the maximum copayments for preferred brand and non-preferred drug tiers, similar to the inflationary adjustment that was finalized for the 2016 plan year. This CY 2019 proposal maintains the current maximum $47 preferred brand tier copayment and the $100 non-preferred brand and non-preferred drug tier copayments, with no adjustment for inflation, despite continued cost trend increases for brand drugs that exceed the Consumer Price Index (CPI) and Part D Annual Percentage Increase (API). The increase in maximum copays from the 2015 to 2016 benefit year (from $45 to $47 for preferred brands and $95 to $100 for non-preferred brands) allowed benefit designs to better account for increasing brand name drug price inflation. In the absence of an increase in the maximum copayments, generic drug tier copayments must increase to maintain basic plan actuarial equivalence to the standard benefit. At the same time, brand name drug manufacturer's annual price increases are insulated from the consumer's economic and behavioral purchasing decisions, because beneficiaries are less aware of the true cost of the drug. Making inflationary adjustments to the maximum preferred and non-preferred brand tier copayments for CY 2019 plans would more accurately account for the increases in brand drug prices.

Improving Drug Utilization Review Controls in Medicare Part D

Opioid Potentiator Drugs

CMS requests feedback on new proposed strategies to more effectively reduce high risk overutilization of prescription opioids in the Part D program. CMS proposes to implement a concurrent opioid-gabapentin/pregabalin flag within OMS. CMS seeks feedback specifically on stakeholder's experience with the potential overuse of potentiator drugs (gabapentin and pregabalin) with opioids, whether the additional flag would be useful for Part D sponsors, and how the case management approach could help with gabapentin/pregabalin-opioid misuse and also with other potentiators.

Comments: **Humana supports the proposed concurrent opioid-gabapentin/pregabalin flag within OMS in order to monitor usage trends and manage utilization.** We support the use of treatment guidelines such as the National Institute on Drug Abuse (NIDA)

Guidelines for Prescribing Opioids, which is aligned with this proposal for managing the potential overuse of potentiator drugs with opioids.[82]

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

CMS proposes that all plan sponsors should implement a hard edit that is triggered when a beneficiary's cumulative daily MME reaches or exceeds 90 MME, excluding medication-assisted treatments such as buprenorphine. Beneficiaries triggering the hard edit should be granted one 7-day supply to use while going through the exceptions process. CMS requests comment on this concept as well as stakeholder feedback on its operational feasibility.

CMS further seeks comment on when and how to best communicate to beneficiaries that the one-time 7-days' supply would not be available for future prescriptions should the MME level remain at 90 mg or higher. CMS seeks feedback on whether all sponsors have the capacity to implement hard edits at 90 MME as well as the proposed 7-days' supply limit for 2019. Comments are also requested on other solutions to address prescription opioid overuse while balancing access to medically necessary drug regimens and reducing the potential for unintended consequences.

Comments: Humana has a 30 year history of providing health and wellness services that incorporate an integrated approach to treating seniors with chronic health conditions. Our approach to the opioid crisis in the Medicare program must address appropriate, evidence-based treatment for Humana members with acute pain or chronic pain, while at the same time combating the country's opioid crisis.

Humana supports edits that align to the CDC Guidelines for Prescribing Opioids for Chronic Pain in the primary care setting. [83] The CDC guidelines address the use of opioids in treating chronic pain (pain lasting longer than three months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care.

Humana supports the use of a 90mg MME hard edit for opioid naïve patients with a one-time 7 days' supply for use while the enrollee goes through the exceptions process. However, we have significant concerns with the proposal which uniformly places a 90 MME hard edit on all beneficiaries, regardless of the duration of their opioid treatment and without regard for the tapering of opioid dosing as outlined in the CDC's companion Guidelines for Tapering Opioids for Chronic Pain.[84] The CDC

[82] Principles of Drug Addiction Treatment: A Research-Based Guide (Third Edition) https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/preface

[83] Guideline for Prescribing Opioids for Chronic Pain. https://www.cdc.gov/drugoverdose/prescribing/guideline.html

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

Tapering Guidelines specifically state that prescribers are to follow-up regularly with patients who are being treated with opioids for longer than three months to determine whether opioids are meeting treatment goals and whether the opioid dosage can be lowered or discontinued. The guidelines advise that opioid tapering plans should be individualized to each patient and should minimize symptoms of opioid withdrawal while maximizing pain treatment with nonpharmacological therapies and non-opioid medications. According to the guidelines, a reasonable starting point for an opioid tapering plan is generally a decrease of 10% of the original dose per week. The guidelines note that some patients who have taken opioids for longer periods of time might find even slower tapers (e.g., 10% per month) easier.

While we support CMS's underlying goal of reducing opioid overutilization, we are concerned that the proposal is not structured to reduce a beneficiary's exposure to chronic high MME opioid doses in a manner that is consistent with the CDC Tapering Guidelines. We are concerned that the proposed policy could cause some of the approximately 500,000 Medicare Part D Program beneficiaries who are currently on an opioid dose that exceeds 120 MME and have been for at least 3 months to experience severe withdrawal symptoms.[85] Subjecting these chronic users of opioids to a 90 MME hard edit, along with existing plan requirements to approve exception requests for these hard edits for the remainder of the plan year, is clinically inappropriate and disconnected from the CDC guidelines. As proposed, we are concerned that beneficiaries will be immediately subjected to a lowering of the MME to <90mg through the exceptions process without an opportunity for the plan to engage with and educate prescribers on the calculation of MME and without an opportunity for prescribers to facilitate tapering the opioid dosage. Conversely, approving the exception request for the existing >90mg MME triggered by the hard edit – which, if approved, is required to remain in effect for the remainder of the plan year – provides no opportunity for the plan to engage with the prescriber to manage opioid tapering as outlined in the CDC guidelines. In other words, exception requests for greater than a 90 MME hard edit are approved for the remainder of the plan year based on a point in time assessment, providing little incentive for the prescriber and member to collaborate and engage in an opioid tapering plan. Neither scenario facilitates a reduction in a beneficiary's exposure to high doses of opioids in a manner consistent with the CDC's opioid tapering guidelines.

Humana's 2018 experience utilizing a 250 MME hard edit supports the concerns we have presented and the clinical disconnect resulting from the utilization of a hard MME edit for chronic, high MME beneficiaries. During the month of January 2018, 1.47% of all opioid utilizing Humana members triggered the 250 MME hard edit and 59% of these members requested an exception. 88.4% of the exceptions requested were approved

[85] HHS OIG Data Brief, July 2017, OEI-02-17-00250. Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing.

for the remainder of the plan year, as the physician statement indicated that the opioid dose was medically necessary.

As an alternative to the use of a 90 MME hard edit for high MME and chronic opioid utilizers, Humana recommends that plans have the flexibility to utilize soft edits to manage the de-escalation of opioid dosages of 90 - 250 MME for chronic users of opioids and to align these soft edits with the CDC Guidelines for Tapering Opioids for Chronic Pain. In addition, we recommend utilizing a hard edit for >250 MME. This hard edit is vital for member and prescriber opioid interventions for the approximately 70,000 Part D Program Beneficiaries with an average daily MED that exceeded 240 mg for an entire year, a dose that is 2.5 times greater than that recommended by the CDC.[86] In 2017, Humana implemented *soft* edits for ≥100 MME and ≥250 MME doses, which could be overridden at the pharmacy counter based on a pharmacist's professional judgement. The number of >100 mg MED daily prescriptions/1000 dropped 18% from 2016 to 2017, and the number of >250 mg MED daily prescriptions/1000 decreased by 24% over this same period. In addition to these soft edits, **we recommend that CMS permit plans to approve exceptions for 250 MME for up to 6 months.** An approval for up to 6 months allows prescribers to initiate an opioid tapering plan to reduce the opioid MME exposure over time, consistent with guidelines.

Permitting plans to use a suite of tools including Medication Therapy Management Programs (MTMP), Level III case management, retrospective drug utilization review (rDUR), and concurrent drug utilization review (cDUR) to support the management of chronic opioid users allows for the implementation of an individualized approach. High touch and individualized interventions through case management and our MTM program target over-utilizing members, guided by risk-based predictive models and clinically appropriate MME levels >90mg based on approved pharmacy and therapeutic committee policy. For example, Humana's 2018 MTM program incorporates an opioid tapering plan of action for targeted interventions that is provided to the prescriber and member, which documents the encounter and goals, and provides guidance to improve the communication between the member and the prescriber. Previous experience with reducing opioid exposure in our opioid management programs indicates that this type of targeted intervention will yield positive results and we look forward to presenting preliminary results in mid-2018.

In addition, Humana conducted an Opioid Provider Consultation Pilot in which Humana pharmacists contacted the top 5,000 outlier prescribers to advise they have patients with high dose opioid use (>120mg MED) and/or members with high dose opioid prescriptions from multiple providers. The goal of the pilot program was to advise prescribers and encourage them to make evidence-based changes to their patients' treatment that aligned with the member's clinical presentation. To ensure program effectiveness, Humana Regional Medical Directors followed up with prescribers who were either unreachable or who made no adjustments to an identified patient's therapy.

[86] Ibid.

Results showed that 17% of providers committed to discontinue opioid therapy based on the information provided in the phone call (e.g., learning that a patient was prescribed opioids by multiple physicians) and 10% committed to changes in prescribed therapy. Targeted, individualized interventions have been shown to be effective in managing and reducing opioid overutilization, and plan sponsors should continue to have the ability to implement these programs with their prescribers and enrollees.

Irrespective of MME edits, in order to implement the proposed opioid 7 days' supply limit in the Part D program, CMS must clarify several existing policies that are barriers to implementing a 7-days' supply limit for the use of opioids in acute pain management.

As noted in Section 30.2.2.2 - Utilization Management Edits Not Requiring CMS Submission and Approval - of Chapter 6 of the Medicare Prescription Drug Benefit Manual, CMS considers safety edits to prevent the dispensing of unsafe dosing of drugs to be part of the concurrent DUR requirements for all Part D drugs.[87] It further states that CMS does not require Part D sponsors to submit point-of-sale (POS) safety related edits as part of their HPMS formulary submission, even if they are implemented as hard edits (with the exception of opioid specific edits, as defined in section 30.2.2.1). Specific safety edits identified in the manual chapter language include: screening for potential drug therapy problems due to therapeutic duplication; age/gender-related contraindications; over-utilization (e.g., early refill) and underutilization; and drug-drug interactions, among others. **Day's supply limits are not included in this section or any other section of Chapter 6.**

Additionally, Chapter 6, Section 30.2.2.1 - Utilization Management Edits Requiring CMS Submission and Approval, stipulates that all of the following utilization management edits require submission to CMS for approval: prior authorization and step therapy edits; quantity limit edits; high cost edits; and opioid-specific safety edits.

Not addressed in the Call Letter, Chapter 6 of the Prescription Drug Benefit Manual, or in other existing CMS guidance is whether this proposed opioid days' supply limit is a utilization management edit that requires submission and approval by CMS under 30.2.2.1 or a safety edit that does not require submission and approval from CMS under 30.2.2.2. **Humana recommends that CMS explicitly clarify both in the Final Call Letter and the subsequent updates to Chapter 6 that opioid days' supply edits are considered safety edits under Section 30.2.2.2 and are not part of the HPMS Part D formulary submission.**

In addition to allowing plans to better ensure that Part D enrollees have access to medically necessary opioid treatment regimens while also reducing the potential for unintended consequences for patient's already on an opioid drug regimen, considering

[87] Medicare Prescription Drug Manual, Chapter 6: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf

this opioid day's supply as a safety edit under 30.2.2.2 will allow plans to structure the edit to prevent the perpetuation of inappropriate use of opioid therapies during an enrollee's transition period. Chapter 6 Section 30.4 details guidance for how PDP sponsors are to provide for an appropriate transition process for plan enrollees and how plans are to apply edits during the transition period. Specifically, Section 30.4.8 states that "edits to promote safe utilization of a Part D drug" as referenced in Section 30.2.2.2 are edits that are appropriate during an enrollee's transition period. Further, Section 30.4.8 states that "beneficiary-level opioid point-of-sale claim edits (and cumulative opioid MME edits, as noted in the guidance on safety edits in Section 30.2.2.2) may be applied during transition." Given CMS's stated interest in addressing prescription opioid overuse in Medicare Part D while also preserving access to medically necessary therapies, considering the day's supply limit as a safety edit in 30.2.2.2 will give PDP sponsors the ability to ensure safe and appropriate access to opioids during the transition period.

Days' Supply Limits for Opioid Naïve Patients

CMS proposes to establish a days' supply limitation policy for opioid naïve patients. CMS requests feedback on the implementation of a 7-day supply limit or whether an alternative days' supply limit would be more appropriate. CMS also solicits comment on whether a days' supply limit with or without a daily dose maximum would be more effective. In particular, CMS requests information on both inclusions and exceptions for specific clinical situations (i.e., whether and to what extent a supply limit could be based on specific indications or other criteria) and other parameters and what safeguards should be in place to protect appropriate beneficiary access.

Comments: Humana supports edits that align with the CDC Guidelines for Prescribing Opioids, including the proposal of a days' supply limitation of 7 days for prescription opioids for naïve patients and recommends a daily dose maximum hard edit up to 90 MME per day for these patients. This recommendation is consistent with a significant increase in the relative risk of non-fatal overdose in this population for MME dosages greater than 90mg, as addressed in the CDC Guidelines for Prescribing Opioids.[88] **Humana recommends that CMS define an opioid naïve patient as a patient with an opioid prescription who has not received opioid treatment over the previous 30 days or longer**.[89] We further support allowing PDP's P&T committees to have the flexibility to develop policies identifying exceptions to this policy to be approved through the exception process for patients with conditions that are outside the scope of the CDC prescribing guidelines addressing opioid therapy in the primary care setting.[90]

[88] Dunn KM, Saunders KW, Rutter CM, et al. Opioid prescriptions for chronic pain and overdose: a cohort study. Ann Intern Med 2010;152:85–92.

[89] MMWR Morb Mortal Wkly Rep. 2017 Mar 17;66(10):265-269. doi: 10.15585/mmwr.mm6610a1.

[90] Mayo Clinic Department of Orthopedic Surgery Adult Opioid Prescription Guidelines- accessed on 2-26-2018 at https://www.mayoclinic.org/diseases-conditions/acl-injury/symptoms-causes/syc-20346173

Opioid Duplicative Therapy Safety Edit

In CY 2019, CMS expects all PDP sponsors to implement a soft POS edit for duplicative long-acting (LA) opioid therapy, with or without a multiple prescriber criterion. Plans will be expected to implement a POS soft edit for the concurrent use of LA opioid therapy and CMS is requesting recommendations on the most effective edit specifications. CMS also seeks feedback on how best to manage multiple opioid POS edits that a single prescription may trigger such as a duplicative therapy and cumulative MME POS edit. In addition, CMS requests feedback on extending the specifications in the future to include short-acting (SA) opioids and defining duplicative therapy as previously described for LA opioids (i.e., generic entity, dosage form, strength and/or differing prescribers) or another unique drug classification scheme (e.g., removing strength).

> **Comments: Humana supports CMS's expectation for sponsors to implement a POS soft edit for concurrent use of LA opioid therapies.** We believe managing multiple opioid POS edits that a single prescription may trigger does introduce complexity and challenges. We recommend that CMS provide plan sponsors with the decision making authority through P&T Committee-developed policy to determine the best way to effectively manage multiple opioid POS edits. We also appreciate CMS exploring the possibility of extending the specifications of this program to include SA opioids in the future. Humana can implement a SA duplicate therapy soft edit but cautions that 10.7% of all SA utilizers would be subject to this duplicative therapy safety edit.

Concurrent Use of Opioids and Benzodiazepines

CMS proposes that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS edit. CMS requests feedback from stakeholders on their experience with concurrent or duplicative soft POS edits including an opioid and benzodiazepine and other drug combinations.

> **Comments: Humana supports CMS's proposal that Part D sponsors implement a concurrent opioid and benzodiazepine POS soft edit.** We have experience with this soft edit and have found that when applied to LA opioids and benzodiazepines, this edit was projected to be triggered almost 40,000 times in January 2018, preventing thousands of concurrent prescriptions from being dispensed. For SA opioids and benzodiazepines, the triggering of this edit is expected to be between 5 to 7 times higher over this same time period.

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

CMS proposes new guidance on how Part D sponsors should determine whether a drug is a Part B covered drug and when plans should revise their findings if information received from CMS changes. These include instances when there is no prior Part D claims history for immunosuppressants, prior Part D claims history and MARx currently indicate that Medicare

covered the transplant, and when there is prior Part D claims history with no MARx indicator or MA plan medical claims history of a covered transplant but the Part D sponsor receives information from CMS that the transplant was covered by Medicare (e.g. Part D sponsor receives the information from CMS as part of a CMS Program Integrity audit or otherwise).

In addition, CMS reiterates that Part D sponsors are permitted to rely on a patient residence code of "3" or "9" on a pharmacy claim for determining when inhalation drugs may be covered under Part D. CMS expects that sponsors will only pay claims for these products when the pharmacy claim includes these specified patient residence codes regardless of any prior coverage determination based upon a prescriber statement indicating that the beneficiary resides in a long-term care facility.

> **Comments: Humana supports CMS's proposal to require best available information to be used when making Part B versus Part D coverage determinations for both immunosuppressants and inhalation DME supply drugs.** Humana appreciates that CMS is willing to remove the substantial burden for MA and Part D plans which results from having to perform a retrospective review. We acknowledge and thank CMS for its collaboration with plans to develop a solution that ultimately benefits our members.
>
> Humana also recommends that CMS provide MA and PDP sponsors with information related to all Medicare-covered transplants. Currently, plan sponsors receive eligibility information on their members who receive Medicare-covered kidney transplants, but lack information for enrollees receiving other organ transplants. Plan sponsors are notified of an enrollee's Medicare-covered kidney transplant through the Transaction Reply Report (TRR) data transfer and Humana encourages CMS to adopt this approach with all other Medicare-covered organ transplants. This approach would also likely reduce, if not eliminate, the intensity of the Program Integrity efforts CMS is currently devoting to this issue by addressing the lack of visibility regarding the appropriate coverage of immunosuppressants, leading to a reduction in CMS and plan sponsors administrative costs.

<u>Part D Mail-Order Refill Consent Policy– Solicitation for Comments</u>

Beginning in 2014, CMS required Part D sponsors to obtain patient consent to deliver via a mail order pharmacy, a new or refill prescription prior to delivery in order to reduce perceived medication waste and the associated costs with unneeded or unwanted prescriptions. CMS made subsequent modifications to the policy that exempted mail-order auto-ship programs in Employer Group Waiver Plans and, in all Part D plans, exempted automatic shipments of new prescription orders received directly from the prescriber, regardless of whether prior patient consent was received.

CMS has requested information and data concerning mail-order auto-ship programs that demonstrate improved medication adherence and clinical outcomes of patients resulting from automatic (not patient-initiated) refills and possible modifications to the current Mail-Order Refill Consent policy.

Comments: Medication nonadherence is a critical concern to Humana clinicians and Medicare Advantage and Part D plans--especially for members living with chronic conditions such as diabetes, high blood pressure, and high cholesterol-- due to its association with adverse outcomes and higher costs of care. The peer-reviewed evidence base substantiates that improved medication adherence has a direct and meaningful impact on the improvement of health outcomes. Participation or enrollment in any programs that improve medication adherence, such as automatic refill programs, should be permitted by CMS and encouraged by Part D plans, clinicians, and pharmacists because of their positive effect on health outcomes measures and improvement in the quality of care delivered in the Medicare program.

Published peer-reviewed literature has shown that the average adherence in patients with diabetes is 67.5% and is lower than that found among patients with many other conditions.[91] A separate systematic review on adherence to medications for diabetes showed that average adherence to oral hypoglycemic agents ranged from 36 to 93%.[92] CMS has responded to these concerns, poor clinical outcomes, and the quality repercussions of medication nonadherence by including measures of medication adherence within the Medicare Part D Star ratings program. These adherence measures have motivated the development of new methods to improve patient adherence. Automatic prescription refill programs are an intervention seeing widespread adoption in recent years. These automatic refill programs anticipate and initiate prescription refills on a standardized, recurrent basis. As a result, prescription refills may be delivered before a patient typically initiates a refill due to exhausting their medication supply. A recent study quantified the effect of an automatic prescription refill program on three adherence metrics used by CMS within Medicare Part D Star ratings. Patients enrolled in the automatic prescription refill program were significantly more likely to be adherent to their medications. The proportion of adherent patients ranged from 73.6% to 76.4% for standard refill cohorts and 77.5% to 83.6% for automatic refill cohorts, and patients in the automatic refill program were significantly more likely to be adherent to the statin, RASA, and diabetes Star ratings ($p<0.05$ for all).[93]

While direct and statistically significant improvement to medication adherence measures has been established by an automatic shipment program in Medicare Part D, CMS requested data other than medication possession ratio (MPR) or proportion of days covered (PDC) measures that indicate actual improved adherence –or actual improvement in health outcomes-- resulting from programs designed to improve medication adherence such as an automatic refill program. The peer-reviewed literature

[91] DiMatteo MRP. Variations in patients' adherence to medical recommendations: a quantitative review of 50 years of research. *Med Care* 42:200 –209, 2004.
[92] Cramer JA. A systematic review of adherence with medications for diabetes. *Diabetes Care* 27:1218–1224, 2004.
[93] Corey A. Lester , PharmD, MS[1*], David A. Mott , PhD[1], Michelle A. Chui , PharmD, PhD. The Influence of a Community Pharmacy Automatic Prescription Refill Program on Medicare Part D Adherence Metrics. J Manag Care Spec Pharm, 2016 Jul;22(7):801-807.

provides direct evidence to support the connection between improved medication adherence and an improvement in clinical outcomes. One such study evaluated whether pharmacy claims-based measures of medication adherence, like PDC, are associated with improved clinical outcomes in patients with diabetes. In this study, even after adjusting for demographic and clinical characteristics, a 10% increase in claims-based measures of nonadherence to metformin and statins was associated with an increase of 0.14% in HbA1c and an increase of 4.9 mg/dL in LDL cholesterol levels.[94] In other words, as nonadherence increases, there is deterioration in HbA1c and LDL levels.

A second study in the literature base found that high adherence (defined as MRP of 80% to 100%) to antihypertensive medications was associated with higher odds (odds ratio 1.45, 95% confidence interval 1.04 to 2.02) of blood pressure control compared with those with medium or low levels of adherence.[95] Similarly, a third study found that each incremental 25% increase in PDC for statin medications was associated with a 3.8-mg/dL reduction in LDL cholesterol.[96] A fourth study evaluated the association between adherence to antidepressants and an effect on clinical outcomes and healthcare costs in patients with major depressive disorder (MDD) and comorbid type 2 diabetes (T2D). This study found a 5-fold improvement in T2D control among diabetic patients with comorbid depression who were adherent to their antidepressants.[97] Further supporting the connection between improved adherence and improvement in clinical outcomes, another study showed that nonadherence to statins in the year after hospitalization for myocardial infarction was associated with a 12% to 25% increased relative hazard for mortality.[98] Finally, another study demonstrated that patients discontinuing clopidogrel within 1 month after hospital discharge for acute myocardial infarction and stent placement were significantly more likely to have an adverse outcome, including re-hospitalization and mortality, in the subsequent 11 months.[99] Similar outcomes were found with poor adherence to heart failure drugs being associated with an increased number of cardiovascular-related emergency department visits.[100]

[94] Manel Pladevall, MD, MS, L. Keoki Williams, MD, MPH, Lisa Ann Potts, PharmD, George Divine, PhD, Hugo Xi, MD, Jennifer Elston Lafata, PhD. Clinical Outcomes and Adherence to Medications Measured by Claims Data in Patients With Diabetes. Diabetes Care 27:2800–2805, 2004

[95] Bramley TJ, Gerbino PP, Nightengale BS, Frech-Tamas F. Relationship of blood pressure control to adherence with antihypertensive monotherapy in 13 managed care organizations. J Manag Care Pharm. 2006; 12:239 –245.

[96] Ho PM, Rumsfeld JS, Masoudi FA, McClure DL, Plomondon ME, Steiner JF, Magid DJ. Effect of medication nonadherence on hospitalization and mortality among patients with diabetes mellitus. Arch Intern Med. 2006;166:1836 –1841.

[97] Vega C, Becker RV, Mucha L, Lorenz BH, Eaddy MT, Ogbonnaya AO. Impact of adherence to antidepressants on healthcare outcomes and costs among patients with type 2 diabetes and comorbid major depressive disorder. Curr Med Res Opin. 2017 Oct;33(10):1879-1889. doi: 10.1080/03007995.2017.1347092. Epub 2017 Aug 2

[98] Rasmussen JN, Chong A, Alter DA. Relationship between adherence to evidence-based pharmacotherapy and long-term mortality after acute myocardial infarction. JAMA. 2007;297:177–186.

[99] Spertus JA, Kettelkamp R, Vance C, Decker C, Jones PG, Rumsfeld JS, Messenger JC, Khanal S, Peterson ED, Bach RG, Krumholz HM, Cohen DJ. Prevalence, predictors, and outcomes of premature discontinuation of thienopyridine therapy after drug-eluting stent placement: results from the PREMIER registry. Circulation. 2006;113:2803–2809.

[100] Hope CJ, Wu J, Tu W, Young J, Murray MD. Association of medication adherence, knowledge, and skills with emergency department visits by adults 50 years or older with congestive heart failure. Am J Health Syst Pharm. 2004;61:2043–2049.

Based on our analysis of member requests to return mail order prescriptions in 2017, we believe proper program design, coupled with a suite of beneficiary protections, is an appropriate balance between driving toward improved health outcomes that programs designed to support medication adherence can provide and CMS's concerns with waste associated with unwanted or unneeded medications.

Humana recommends three components to a well-designed automatic refill program, based on analysis of our internal data and experience. Less than 0.001% of prescriptions originated and dispensed by a network mail order pharmacy resulted in a complaint (CTM) and less than 0.3% of claims were requested to be returned, with 90% of all return requests honored. The 10% of requests that were not honored were generally associated with members who initiated a refill request but later decided they no longer wanted the medication. Our data also indicate that our return policy is liberal and robust with only 2% of members who made refund request also making subsequent requests for a refund. This is primarily due to functionality within our system's member interface that allows enrollees to set additional parameters within their account to stop shipments that exceed a dollar threshold without additional review and authentication by the member before the prescription is dispensed and delivered.

We believe that beneficiaries who affirmatively opt-in to an automatic refill program behaviorally self-select for this service which will mitigate CMS concerns related to medication waste, returns of unneeded or unwanted mediation, and beneficiary complaints. As such, **our first program recommendation is that a Medicare automatic prescription refill program should be designed as an opt-in beneficiary enrollment program without requirements to obtain prior patient consent to deliver a refill prescription before each mail order pharmacy delivery.**

Second, mail order pharmacies should utilize an electronic (text, email, smart app technology etc.) or telephonic refill reminder notification system to allow beneficiaries enrolled in the program to notify the mail order pharmacy that an individual prescription refill is not needed or wanted. Utilizing these types of message systems can themselves also lead to medication adherence. In fact, a recently published study found that medication adherence rates were 14% higher for Medicare patients living with chronic conditions receiving refill reminders via text message through which they could take action to order a refill prescription. Not only were adherence rates higher, enrollees receiving the text reminders reported a high-quality user experience and found the reminders easy to use.[101]

Third, mail order pharmacies should have a return policy that provides a specific safeguard allowing beneficiaries to return medications to the pharmacy in the event

[101] Rena Brar Prayaga , MA, JD; Erwin W Jeong , PharmD; Erin Feger , BA; Harmony K Noble , BA; Magdalen Kmiec , BA; Ram S Prayaga , MS. Improving Refill Adherence in Medicare Patients with Tailored and Interactive Mobile Text Messaging: Pilot Study. JMIR Mhealth and Uhealth. 2018:6:1-10. http://mhealth.jmir.org/article/download/mhealth_v6i1e30/2

that a new prescription initiated by a prescriber is unneeded or unwanted. The refund policy should also be structured to encourage member disenrollment from the automatic refill program as an option to prevent future instances of the receipt of automatic refills.

Additional Issues Not Addressed in the Advance Rate Notice and Draft Call Letter

Revisions to Timing and Method of Disclosure Requirements (§§422.111 and 423.128)
In the recent MA and Part D proposed rule, CMS proposed to simplify the disclosure requirements in §§422.111 and 423.128 by allowing for flexibility in how the Evidence of Coverage (EOC) is made available to enrollees.

Comments: We would like to reiterate our support for the proposed change. In addition, we respectfully request that CMS include the LIS Rider as part of this change in flexibility. Humana agrees that, similar to the approach with Provider/Pharmacy Directories and Formulary, a notice be sent to enrollees to provide them with the option of either accessing the EOC and LIS Rider online or requesting a hard copy version of the document.

In order to facilitate this disclosure, we recommend an additional alternative to sending a separate, distinct notice to enrollees. **Humana recommends that the model Annual Notice of Change be updated to include an optional page for plans to explain, in detail, how enrollees can access important documents, including the EOC, Provider/Pharmacy Directories and Formulary.** Allowing plans to include this pertinent information within the ANOC ensures:

- All information is contained in one document for easy enrollee accessibility, eliminating opportunities for separate documents to be misplaced; and

- Reduction in the number of mailings, especially large size documents, plans are required to mail to enrollees, which has proven to be overwhelming to enrollees through consumer testing noted in this proposed rule

Appointment of Representative (AoRs) and Waivers
Existing CMS rules for waivers and AoRs at Chapter 29, section 270.1.2 of the Medicare Claims Processing Manual require a stamped or ink signature and thus, do not allow plans to implement e-signature functionality.

Comments: We recommend streamlining the process by incorporating an AoR signature into the Appeal request form so that it can be captured upfront from non-digital users. We are also looking for ways to capture these forms upfront for our ever-growing digital user audience. As we move toward simplifying our process for members and providers, digital submissions for grievance and appeals could provide a transparent and quick way to handle these complaints. However, to enable this capability, Humana

would like the ability to accept an electronic signature for AoRs and waivers. Without the ability to accept electronic signatures for these forms, members and providers won't be able to fully realize the benefits of digital submissions. Through research, we have learned that members are confused and upset when they are sent offline to do a task from an online form, leading to a disjointed experience for the members and caregivers using the system. Electronic signatures will allow Humana to provide an enhanced member and provider appeal experience that will expedite the process, allowing appeals to be addressed more timely and completely.

Last year Humana processed 40,000 AoRs and waivers. A waiver/AoR request adds between 3-12 days to the process for post-service cases (due to time related to mailing and receiving the form). By implementing electronic signatures, MA plans could recognize a savings of approximately $60 per case by eliminating the need to request the waivers and send them back through the sorting process. Assuming that waiver and AoR volumes are flat moving forward (with 100% adoption of electronic signature), MA plans could save millions of dollars per year in administrative costs that would be passed along to our members via lower premiums and/or additional benefits.

When provider offices have to complete waivers, not only does it delay resolution on the case they are appealing, but it also comes with administrative overhead. In 2016 we received approximately 32,000 waivers from providers. Assuming it takes around 15 minutes for a provider's office to process a waiver (receiving it in the mail, reviewing it, signing, and sending back to us), that is equivalent to an estimated 4 FTEs spread across all of our providers. Additional costs for providers include the cost to mail the forms back to us, and the loss of the potential payments providers would receive for cases that are closed due to non-receipt of waivers.