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January 16, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244
Submitted electronically via regulations.gov

RE: CMS–4182–P

Dear Administrator Verma:

This letter is in response to the Centers for Medicare and Medicaid Services (CMS) request for comments regarding the "Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program" proposed rule published in the November 28, 2017, *Federal Register*. Humana is pleased that CMS has stated with the release of this proposed rule a commitment "to making sure that our seniors have more choices and lower premiums in their Medicare Advantage plans" and "to reducing unnecessary regulations that have driven up the cost of healthcare without improving care, so we are eliminating burdensome regulations on plans and providers that have stood in the way of providing quality patient care."[1]

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 3.29 million members and Medicare Prescription Drug Plans (PDPs) with approximately 5.29 million members, we are distinguished by our 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.

[1] CMS releases proposed rule to increase choices and lower premiums for Medicare Advantage enrollees https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-11-16.html

In summary, Humana is pleased and supportive of the many proposals for reduced administrative burden and regulatory flexibility, including the provisions for: 1) segment benefit flexibility; 2) elimination of Medicare Advantage meaningful difference requirements and modification of Part D meaningful difference requirements; 3) notice and comment process for future Star Ratings changes; 4) tiering exceptions; 5) long-term care transition fills, 6) midyear formulary changes; 7) electronic Evidence of Coverage; 8) lengthening adjudication timeframes for Part D payment redeterminations and Independent Review Entity (IRE) reconsiderations; 9) elimination of MA plan notice for cases sent to the IRE; and 10) reducing the burden of Medical ;Loss Ratio requirements. While we have numerous technical suggestions, our greatest concerns focus on the following two areas:

1. **Reporting Direct and Indirect Remuneration (DIR) at Point of Sale (POS)** – CMS outlined potential future policies involving both drug manufacturer and dispensing pharmacy DIR being reported at POS. Humana does not support these outlined policies because they would increase premiums, while yielding a windfall to drug manufacturers by reducing their coverage gap discount program liabilities. We can find no evidence that such policies would yield sustainable savings for the majority of beneficiaries. President Trump, Administrator Verma, and Food and Drug Administration Commissioner Gottlieb have all spoken to the importance of competition in reducing drug prices. Humana agrees and we urge CMS to work with other Executive Branch agencies to crack down on the anticompetitive behavior of certain drug manufacturers and to ensure robust competition in the prescription drug markets; and

2. **Seamless Conversion and Passive Enrollment of Dual Eligibles** – Humana is supportive of policies that seek to integrate care for duals. However, this goal should be balanced with rules that ensure consumers are actively choosing the coverage that best meets their needs.

As always, we value this opportunity to provide comments and are pleased to answer any questions you may have with respect to the technical comments below.

Sincerely,

Mark A. Newsom
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II.A.1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions (§§ 423.100 and 423.153)

CMS proposes to implement statutory provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA), which provide a framework under which Part D plan sponsors may establish a drug management program for at risk beneficiaries' access to coverage of "frequently abused drugs" to a selected prescriber(s) and/or a network pharmacy(ies).

CMS also proposes to codify the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) by integrating current policy with proposals for implementing the drug management program provisions.

Frequently Abused Drugs (§ 423.100)

CMS proposes to designate all opioids as "frequently abused drugs," except buprenorphine for medication-assisted treatment (MAT) and injectables. CMS further proposes to exclude benzodiazepines, muscle relaxants, or other non-opioid controlled substances from the definition of "frequently abused drugs." In addition, CMS proposes that, if finalized, the new rules would supersede current OMS policy and sponsors would no longer be allowed to implement existing OMS controls for non-opioid medications.

> **Comment: As CMS seeks to implement the CARA lock-in provisions, we urge the agency, above all else, to do no harm. We are concerned that the existing proposal does not comply with this central tenet. While we commend CMS for designating opioids as a "frequently abused drug," we do not support excluding all other controlled substances. The statute explicitly authorizes the Secretary to allow lock-in programs for any controlled substance that the Secretary deems to be frequently abused or diverted. The statute does not limit the definition of a "frequently abused drug" solely to Schedule II controlled substances. As a result, we strongly encourage CMS to permit lock-in programs for benzodiazepines, which the agency's own research has identified as a significant health threat to Medicare beneficiaries.[2] In addition, we encourage CMS to work with Congress to permit plans to extend lock-in programs to frequently abused, non-controlled substances, including skeletal muscle relaxants.**
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> **In the interim, we strongly recommend that plan sponsors be allowed to continue their existing OMS controls for non-opioid drugs. These controls are in place to reduce utilization of drugs that pose a direct health risk to Medicare beneficiaries. We question why CMS would require plans to eliminate these programs given that the CARA statute makes no reference to limiting or eliminating existing OMS programs.**

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

Clinical Guidelines (§ 423.100)

CMS proposes that clinical guidelines for use in drug management programs would be the OMS criteria established for plan year 2018. Under this proposal, sponsors would not be able to vary the criteria of the guidelines to include more or fewer beneficiaries in their drug management programs; although sponsors would continue to be permitted to apply the criteria more frequently than CMS would apply them.

> **Comments: Humana is concerned that CMS's proposed guidelines appear to be aimed primarily at limiting the size of lock-in programs, rather than permitting scientific evidence and clinical research to dictate the most appropriate clinical guidelines. We recommend that plan sponsors be given the flexibility to establish and update targeting criteria and program features based on evolving clinical evidence and the specific needs of our members.**

Multiple Location Pharmacies (§ 423.100)

For purposes of determining the number of opioid dispensing pharmacies under the proposed clinical guidelines, CMS proposes treating multiple locations that share real-time electronic data as one pharmacy.

> **Comments: We support the proposal that chain pharmacies, having multiple locations that share real-time electronic data, be collectively treated as a single pharmacy under the clinical guidelines.**

Exempted Beneficiaries (§ 423.100)

CMS proposes to exclude from the drug management program those beneficiaries residing in a long term care (LTC) facility, receiving hospice care and/or those beneficiaries with a cancer diagnosis.

> **Comments: We support the agency's proposal and appreciate that the agency did not propose exempting additional categories of beneficiaries from the drug management program.** Plans have the same administrative challenges as CMS in identifying beneficiaries residing in other health care facilities, such as group homes and adult day care centers. **In order to effectively and efficiently operationalize the exemption for beneficiaries who live in LTC facilities, plans sponsors will need the Long Term Institution (LTI) report to be released on a more frequent monthly basis rather than the current quarterly basis.**

Prescriber Agreement (§ 423.153(f)(2))

Before implementing a pharmacy lock-in, CMS proposes to require plan sponsors to obtain the agreement of the prescribers, unless the prescribers were not responsive to the required case management.

> **Comments: Humana supports requiring that prescribers and pharmacies agree to participate in a drug management program before it is implemented for an at-risk**

beneficiary. However, we do not support CMS's proposal that plan sponsors be required to reach out to prescribers in order to further verify whether a potentially at-risk beneficiary is deemed at-risk and eligible to participate in a *pharmacy* lock-in program. This will create additional administrative burden and inefficiencies for plan sponsors, pharmacies, and prescribers. For example, we can expect that some prescribers will become unnecessarily burdened with initial and potential follow-up phone calls from numerous plan sponsors.

Prescriber verifications should not be required for a pharmacy lock-in; instead, plan sponsors should be able to identify at-risk beneficiaries based on well-established clinical guidelines, and then implement a pharmacy lock-in after providing the requisite notice.

Beneficiary Notification (§§423.153(f)(6) and 423.153(f)(6)(8))

CMS proposes to require that plan sponsors provide written notice to a potential at-risk beneficiary if the plan intends to limit access to coverage.

Comments: Humana recommends that CMS allow limited exemptions to the 30-day timeline between the initial and second beneficiary notice. The current proposal is unnecessarily rigid and would prevent plans from implementing a lock-in program more quickly in cases of egregious and potentially dangerous overutilization or in cases involving an active criminal investigation when allowed by a court. We do not believe this was the agency's intent. Section 1860D-(4)(c)(5)(B)(iv)(II) of the Social Security Act as amended by CARA explicitly authorizes the Secretary to authorize plans to provide the second notice on an earlier date if there are concerns regarding the health or safety of the beneficiary or in cases of suspected drug diversion. We urge CMS to utilize its statutory authority to permit limited exceptions to the 30-day timeline.

We also note that the beneficiary notice requirements in CARA apply only to lock-in programs – not beneficiary-specific claims edits. We encourage CMS to clarify this fact in the final rule.

Waiting Period (§ 423.153(f)(4))

CMS proposes to require that plan sponsors wait six months from the date a beneficiary first appears on the OMS report before initiating a prescriber lock in.

Comments: Humana has serious concerns about the lengthy six-month waiting period before plans can limit access to coverage of frequently abused drugs to a selected prescriber. A six-month waiting period defeats the underlying purpose of the prescriber lock-in program. It is critical that at-risk beneficiaries be enrolled into the appropriate lock-in program for their clinical situation as soon as possible in order to improve coordination of services and address their prescription drug abuse. The success of the program depends on how quickly patients are identified and connected to an

intervention. Without a timely intervention, patients will continue to inappropriately utilize opioids.

Instead, we recommend that plans be permitted to establish a prescriber lock-in concurrently with the Morphine Milligram Equivalent (MME) beneficiary-level edit. By requiring plans to separately contact the prescriber for the MME edit and the lock-in, CMS is imposing an unnecessary administrative burden on prescribers, who will likely be fielding calls from multiple plans.

Additionally, we recommend that CMS waive the six-month waiting period for beneficiaries enrolled in Medicaid lock-in programs immediately prior to becoming eligible for Medicare. While we acknowledge that newly eligible beneficiaries would have insufficient OMS data to meet the proposed clinical guidelines, CMS should provide a special exception to those requirements in cases where the beneficiary was enrolled in a Medicaid lock-in program with similar or more stringent eligibility requirements than the proposed OMS-based criteria.

Beneficiary Preference (§§423.153(f)(9) and 423.153(f)(10))

CMS proposes that, in addition to the beneficiary preference provisions contained in CARA for selecting a prescriber or pharmacy, the selected prescriber or pharmacy must be in-network. However, if the beneficiary is a PDP member and requires a selected physician, the plan sponsor must generally select the prescriber that the beneficiary prefers, unless an exception applies. CMS proposes that the sponsor must inform the beneficiary of the selection. CMS also proposes that if the sponsor determines that the beneficiary preference would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary, the sponsor may change the selection without regard to the beneficiary's preferences if there is strong evidence of inappropriate action by the prescriber, pharmacy or beneficiary and if the sponsor provides the beneficiary with at least 30 days advance written notice of the change and a rationale for the change.

CMS notes that it is not limiting the number of times a beneficiary can submit their preferences, but is seeking comment on whether a limit should be created. Furthermore, CMS proposes that if beneficiaries do not submit their preferences, the sponsor may make the selection on a beneficiary's behalf as long as reasonable access is accounted for.

Comments: Humana supports CMS's proposal to require that a selected prescriber or pharmacy be in-network. We also support the agency's proposal to allow plan sponsors to change a beneficiary's selection if there is strong evidence of inappropriate action by the prescriber, pharmacy, or beneficiary. In response to CMS's request for feedback on whether a limit should be created for the number of times a beneficiary can submit their preferences, we recommend capping the number of times a beneficiary can submit their preferences to three times per year.

Termination of a Beneficiary's Potential At-Risk or At-Risk Status (§ 423.153(f)(14))
CMS proposes to limit lock-ins and beneficiary-specific point of sale (POS) edits to a maximum period of 12 months.

> **Comments: While we agree that a beneficiary's participation in a lock-in program should be reevaluated after 12 months, we do not believe that CMS should explicitly prohibit plans from extending a lock-in period beyond 12 months if clinically justified. The individual needs of beneficiaries should supersede arbitrary timeframes. Recovery from opioid addiction can take months, and even years.[3] Individual results are highly variable and relapse is common.[4] We are concerned that the proposed policy appears to be predicated on the idea that lock-in programs are punitive. On the contrary, lock-in programs have the potential to become an integral component of a beneficiary's comprehensive treatment plan, assisting in the journey to recovery. We share similar concerns regarding CMS's proposal to limit beneficiary-specific POS edits to a maximum period of 12 months.**

I.A.2. Flexibility in Medicare Advantage Uniformity Requirements (§ 422.100(d))
For the 2019 plan year, CMS proposes to clarify that the agency has the authority to permit MA organizations to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees are treated the same.

> **Comments: Humana appreciates the agency's ongoing efforts to review existing regulations and consider how the MA program can better achieve its goals for providing high quality, cost-effective care to beneficiaries. Humana supports the proposed changes allowing plans greater flexibility in the design of benefits for individuals that meet specific medical criteria. The proposal would be a significant change to the development and operations of MA plans, and as a result, Humana proposes CMS implement the proposed changes starting with the 2020 contract year bid submission.** This will ensure Medicare Advantage Organizations (MAOs), CMS, and providers have appropriate time to implement any changes necessary to comply with the new guidance.
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> In addition, Humana recommends consideration of the following issues as CMS seeks to implement the proposal:
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> - The current proposal may create confusion for beneficiaries since a beneficiary would now need to consider how health conditions affect benefits when choosing an MA plan. We encourage CMS to work cooperatively with MAOs and other key stakeholders to develop strategies to better inform beneficiaries about these new benefit designs.

[3] https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse
[4] https://www.ncbi.nlm.nih.gov/pubmed/20669601

- Providers may not be aware of recent updates to a beneficiary's health status, which could result in providers collecting incorrect cost sharing at the point of service. Some health conditions need to be periodically re-confirmed by a physician, and if this confirmation does not occur, the beneficiary may unknowingly switch between different coverages and benefits.
- MAOs will need sufficient time to enhance their existing internal tools and systems to accommodate varying benefit structures for different sub-populations within a single plan. In addition, MAOs' tools and systems will need to interface with any revisions to CMS provided tools (e.g. PBP, out-of-pocket cost (OOPC) Model). The CMS tools are not yet available for testing, and presumably would not be available for a few more months, making it extremely challenging for MAOs to implement revisions to effectively interface with CMS systems. In order to ensure a smooth rollout for beneficiaries, we reiterate our recommendation to delay implementation of the agency's proposal until the 2020 contract year bid submission.

Humana also urges CMS to consider extending benefit and cost sharing flexibility to supplemental benefits targeted at addressing the social determinants of health (SDOH). In our comments for the Center for Medicare and Medicaid Innovation's (CMMI) Request for Information (RFI), we urged that demonstration authority be leveraged to test MA supplemental benefits targeted at the SDOH. However, we believe if CMS finalizes the proposed flexibilities regarding interpretation of the uniform benefits provision of the Social Security Act, then the agency could revise manual chapters and other sub-regulatory guidance to allow for supplemental benefits aimed at addressing the SDOH.

The literature clearly demonstrates that health is influenced by more than just medical-specific factors.[5] 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.[6] As such, **we believe that if CMS finalizes this proposed benefit flexibility, the agency**

[5] 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.

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

should immediately release updates to Medicare Managed Care Manual Chapter 4, Section 30, allowing for benefit designs that will address food insecurity and social isolation. To be clear, we are asking for updated chapter language 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 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 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.[7] 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. Supplemental benefits are categorized as either mandatory or optional, each regulated differently. Mandatory supplemental benefits are benefits that are not covered under Part A, Part B, or Part D but are covered by the MA plan for every person enrolled in the MA plan. Mandatory supplemental benefits are paid for either in full, directly by, or on behalf of, MA enrollees by premiums and cost-sharing, or through the application of rebate dollars. Optional supplemental benefits are benefits not covered under Part A, Part B, or Part D, but are offered uniformly to all enrollees. Enrollees may choose to pay extra to receive coverage under the optional supplemental benefit. The optional supplemental benefit is paid for directly by the enrollee or on behalf of the enrollee through an additional premium and cost-sharing. Rebate dollars may not be applied toward optional supplemental benefits.[8]

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.[9] 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

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

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

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

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).[10]

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.[11]

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;[12]" 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.

Social isolation: Social isolation, loneliness 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.[13] According to research from the AARP Foundation, 17% of adults age 65 and older are isolated, leading to a 26% increased risk of death due to the subjective feeling of loneliness.[14] One of the biggest risk factors for social isolation is challenges with or lack of access to transportation. Seniors

[10] See http://apps.humana.com/marketing/documents.asp?file=3105791
[11] Chapter 4, Medicare Managed Care Manual, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf
[12] 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/
[13] HHS, "Healthy People 2020 and Social Determinants of Health," available at https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health
[14] See https://connect2affect.org/

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 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."[15] 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.

I.A.3. Segment Benefits Flexibility

CMS has determined that the statute and existing regulations may be interpreted to allow MA plans to vary supplemental benefits, in addition to premium and cost sharing, by segment, as long as the benefits, premium, and cost sharing are uniform within each segment of a MA plan's service area. Plan segments are county-level portions of a plan's overall service area which, under current CMS policy, are permitted to have different premiums and cost sharing amounts as long as these premiums and cost sharing amounts are uniform throughout the segment. CMS proposes to revise its interpretation of statute and regulations to allow MA plan segments to vary benefits in addition to premium and cost sharing.

Comments: Humana supports the CMS proposal to allow further flexibility across segments.

I.A.4. Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 417.454 and 422.100)

All MA plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)), must establish limits on enrollee out-of-pocket cost sharing for Parts A and B services that do not exceed the annual limits established by CMS. CMS proposes to amend the regulation text to permit annual adjustment of the mandatory and voluntary maximum out-of-pocket (MOOP) limits based on changes in market conditions and to ensure the sustainability of the MA program and benefit options. The proposed new authority permitting changes in data and methodology related to establishing MOOP limits would be exercised by CMS in advance of each plan year; CMS would use the annual Call Letter and other guidance documents to explain

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

its application of this proposed regulatory standard and the data used to identify MOOP limits in advance of bid deadlines. CMS predicted possible use of MA encounter data in the future.

> **Comments: Humana supports the proposed change in requirements that would afford CMS flexibility in establishing annual MOOP limits.** We agree that this authority is warranted in order to promote sustainability of the MA program and benefit options. In particular, an increase in the voluntary MOOP limit would allow plans more flexibility with A/B cost shares and likely increase the number of plans offering a voluntary MOOP. Humana also believes that the CMS proposal is generally consistent with past practice from the Call Letter and we have no concern codifying the process. **With respect to leveraging encounter data however, the Government Accountability Office (GAO) and many plans have reported various systems and data quality issues.[16] While we are encouraged and are supportive of CMS's attempts to work with plans to improve data quality, we do believe there is much work left to be completed. Until those issues are resolved and the data quality is verified by independent third parties like GAO, we do not believe that it would be appropriate to use these data alone for establishing MOOP levels.**

I.A.6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§ 422.254 and 422.256)

For the 2019 Plan year, CMS has proposed to remove §§ 422.254(a)(4) and 422.256(b)(4) to eliminate the meaningful difference requirement for MA bid submissions. CMS seeks comments and suggestions on the topics discussed in this section to ensure beneficiaries have access to innovative plans that meet their unique needs.

> **Comments: Humana supports the CMS 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 this proposal will allow sponsors to better design plans around current and future beneficiary needs, as opposed to designing plans to meet actuarial calculations.
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> We appreciate the agency's comments on the factors that will prevent plan counts from increasing; however, we encourage CMS to monitor the number of plan choices and the potential for confusion that may occur when beneficiaries search for an MA plan. We believe CMS should closely monitor any expansion of the number of plan offerings to ensure that additional value is being created in the market. Also, in an effort to support beneficiary decision making, Humana recommends CMS work with MAOs to identify benefits that are not accurately or clearly represented on Medicare Plan Finder (MPF). Examples include incomplete information on deductibles for medical and pharmacy

[16] Limited Progress Made to Validate Encounter Data Used to Ensure Proper Payments GAO-17-223: Published: Jan 17, 2017, available online at https://www.gao.gov/products/GAO-17-223

benefits. Currently, beneficiaries cannot easily discern benefits that are excluded from the medical deductible (e.g. all in-network services for preferred provider organizations (PPOs)). Additionally, MPF is not explicit in terms of which drug tiers do or do not apply to the Part D deductible.

Humana agrees with the proposal to maintain requirements to prevent MAOs from misleading beneficiaries in communication materials, for disapproval of a bid if the benefit design substantially discourages enrollment by certain Medicare-eligible individuals, and for non-renewing plans that fail to attract a sufficient number of enrollees. We request that CMS clearly define and publish the criteria for determining if a bid will be disapproved because the benefit design substantially discourages enrollment. In addition, we request CMS define how it will be determined if a plan will not be renewed due to failing to attract a sufficient number of enrollees over a sustained period of time, if they differ from current requirements. Defined criteria will assist MAOs in ensuring they minimize the number of disapproved bids and non-renewed plans. Without the criteria, unintended member disruption may occur if MAOs are not aware of how CMS will determine when to disapprove a bid or non-renew a plan for the following contract year. CMS should publish the proposed criteria in the Draft Call Letter, with comments solicited at that time.

Due to the limitations, as noted by CMS, of the current standardized meaningful difference evaluation, Humana recommends that CMS review the Total Beneficiary Cost (TBC) standard methodology which leverages the meaningful difference evaluation. The model may not accurately evaluate some plan changes so the calculated change in TBC may be inconsistent with the change in benefit value perceived by beneficiaries.

II.A.7. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68)

CMS proposes that MA organizations can process default enrollments only for dual-eligible individuals in states where the contract with the state approves it and the state identifies eligibility and shares necessary data with the organization. To ensure that Medicaid beneficiaries considered for default enrollment upon their conversion to Medicare are aware of the default MA enrollment and of the changes to their Medicare and Medicaid coverage, CMS also proposes that the MA organization must issue a notice no fewer than 60 days before the default enrollment effective date to the enrollee. CMS finally proposes that MA organizations must obtain approval from CMS before implementing default enrollment.

Comments: Humana supports the goal of integrating Medicare and Medicaid benefits for dually eligible beneficiaries. However, we have some concerns with these proposals. First, not all managed Medicaid entities currently offer Dual Eligible Special Needs Plans (D-SNPs) and some D-SNPs offered by managed Medicaid entities may not have the same level of MA experience, Star Ratings, and/or plan benefits as D-SNPs offered separately in the market. Second, CMS has the exclusive regulatory authority over enrollment in the Medicare program. These proposals appear to share that authority, to

some degree, with state Medicaid agencies. We urge CMS to retain its exclusive jurisdiction over D-SNP enrollment policy and to focus on ensuring that dual eligible consumers are actively choosing the coverage that best meets their needs. Should CMS decide to move forward with these proposals we recommend that implementation be delayed to synch with Congressional SNP reauthorization and that the 60-day notice should include other MA options available, which would be consistent with non-renewal notice requirements.

II.A.8. Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (§ 422.60(g))

CMS is proposing to add authority to passively enroll full-benefit dually eligible beneficiaries who are currently enrolled in an integrated Dual-Eligible Special Needs Plan (D-SNP) into another integrated D-SNP when all the following conditions are met:

- when necessary to promote integrated care and continuity of care;
- where such action is taken in consultation with the state Medicaid agency;
- where the D-SNP receiving passive enrollment contracts with the state Medicaid agency to provide Medicaid services; and
- where certain other conditions are met to promote continuity and quality of care.

Comments: Humana understands the challenges dual eligible individuals face in navigating both Medicaid and Medicare programs. In 2017, Humana offered D-SNP plans in 22 states; in two of these states we also held a Medicaid and/or managed LTC contract, and in two others, we participated in the CMS Financial Alignment Initiative demonstration program. In the 11 years we have offered D-SNPs, we have continuously worked to improve coordination of care and benefits for our dual eligible members. As a result of these and other quality improvement efforts, 83% of Humana's current D-SNP members are in 4+ star plans.[17]

We appreciate the desire to ensure continuation of integrated Medicaid and Medicare benefits – particularly when a dual eligible beneficiary's managed Medicaid or D-SNP plan is no longer offered in the market, either due to an unsuccessful state managed Medicaid/managed long-term services and supports (MLTSS) procurement bid or because a health plan chooses to no longer offer a D-SNP in the region. In these situations, we generally approve the expansion of authority to allow passive enrollment to a managed Medicaid/MLTSS and D-SNP from the same parent company, provided both entities meet quality standards as envisioned in the proposed rule. For D-SNPs, we favor quality standards commonly used today for managed care organizations (MCOs), such as Healthcare Effectiveness and Data Information Set (HEDIS) measures, and for MA plans, such as Star Ratings and beneficiary satisfaction with their plan.

Beneficiary advocates have been critics of passive or seamless enrollment. For example, the Medicare Rights Center and other advocacy groups have stated that "CMS should

[17] SNP Comprehensive Report – November 2017 and 2017 Overall Star Ratings

advance policies that encourage people new to Medicare to make an active and informed choice about the coverage option" and have urged "the agency to proceed with caution and to allow this practice in only the most limited circumstances." [18] Humana believes these concerns are reasonable. **Accordingly, Humana recommends that CMS implement the proposal only in those states where the Medicaid agency specifically links Medicaid plans to D-SNPs, requiring contracted Medicaid or MLTSS MCOs to offer a complimentary D-SNP plan with an aim of integrating coverage and benefits, and limits D-SNPs contracts to these MCOs**. This option serves to maintain the desired continuity of coverage between plans offered by the same parent company (preserving the intent of both the state procurement design and CMS's aim of avoiding gaps in coverage and supporting coordinated, integrated care). This also allows states without a comprehensive MLTSS or managed Medicaid program to maintain a level playing field among different coverage options and choice for dually eligible beneficiaries among MA and D-SNP plans. CMS should also ensure that beneficiaries are provided information on all plan options and are aware of their rights to make their own choice of coverage.

Separately, we caution against proposals that would restrict passive enrollment to MA plans that operate as a Fully Integrated Dual Eligible SNP (FIDE-SNP) at this time as we are concerned that this would skew the market towards plans that are not commonly offered across most parts of the country. Over the years, we have approached several states about the FIDE-SNP options and have found some to be hesitant to enter into FIDE-SNP arrangements due to the additional time and administrative burden involved. The fact that only 8 of 43 states with D-SNP contracts currently include FIDE-SNPs suggests that our experience is not unique.

II.A.9. Part D Tiering Exceptions (§ 423.560 and § 423.578(a) and (c))

CMS is proposing various changes to § 423.560 and § 423.578(a) and (c) related to the requirements for plan adjudication and effectuation of tiering exceptions. These changes include establishing a revised framework for the treatment of tiering exception requests based on whether the requested drug is a brand name drug, a generic drug, or a biological product and where the same type of drug alternatives are located on the plan's formulary. The proposed changes also include clarification of appropriate cost-sharing assigned to approved tiering exception requests when preferred alternative drugs are on multiple lower-cost tiers.

Comment: Humana supports the proposed changes to Part D tiering exceptions policy. Specifically, we appreciate the revision of § 423.578(a)(6)(i), which specifies that a Part D plan sponsor will not be required to provide a tiering exception for a brand name drug to a preferred cost-sharing level that applies only to generic or authorized generic drug alternatives for treating an enrollee's condition. In addition, Humana supports the proposed new paragraph § 423.578(a)(6)(ii), that permits plans to limit the availability of

[18] Letter from the Medicare Rights Center, Justice in Aging, Center for Medicare Advocacy, and National Council on Aging to CMS, available online at http://medicarerights.org/pdf/cms-letter-seamless-conversion-093016.pdf

tiering exceptions for biologic drugs to a preferred tier that contains the same type of alternative biologic drug(s) for treating an enrollee's condition. Lastly, we appreciate the revised and re-designated § 423.578(a)(6)(iii), that permits Part D sponsors to exclude tiering exceptions for any drug that is on the plan's specialty tier (currently codified at § 423.578(a)(7)).

CMS cites in the proposal that "the current regulations are no longer sufficient to ensure that tiering exceptions are understood by beneficiaries and adjudicated by plan sponsors in a manner the statute contemplates." CMS states this as the main reason for the simplification of the tiering exceptions policy proposed in § 423.578(a)(6) – which Humana supports. However, we believe CMS's clarification that the specialty tier is not exempt from being considered a preferred tier for purposes of tiering exception requests will create confusion for beneficiaries. The proposed clarification runs counter to the notion of making tiering exceptions more easily understood by beneficiaries because it creates a paradoxical nuance whereby a specialty tier drug is exempt from teiring exceptions, but specialty tier cost sharing is subject to tiering exception policy. Therefore, we recommend CMS finalize that a Part D plan sponsor may design its exception process so that both specialty tier drugs and specialty cost sharing are not eligible for a tiering exception.

II.A.10. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (§ 423.38)

CMS proposes to discontinue the continuous SEP available to dual eligible and other low income subsidy (LIS) beneficiaries, and in its place implement a narrower set of criteria LIS beneficiaries must meet in order to be eligible for an SEP. These criteria include:

- allowing a once per year SEP for LIS beneficiaries to be used at any time during the year so long as that beneficiary has not been identified as being at a high risk of opioid abuse;
- creating a new, one time SEP for beneficiaries auto enrolled in a plan, to be available prior to, or within two months of their effective date; and
- creating a new SEP for beneficiaries experiencing a change in their LIS status within two months of the change, or of being notified of a change.

CMS purports that such changes will help dis-incentivize opioid abuse, chronic switching, and marketing abuses, while creating a more stable managed care infrastructure for LIS beneficiaries.

Comments: Humana supports the CMS goals of limiting chronic plan switching and other abuses within the LIS population. As CMS notes, frequent disenrollment prevents plan sponsors from maximizing the benefits of integrated care for the beneficiary, the sponsor, and the Medicare program. In addition, Humana agrees that this is a unique population with unique needs, and any changes to SEP criteria should allow enough flexibility for beneficiaries to make appropriate choices based on their needs. **Though Humana is supportive of the underlying policy goals, we feel the current proposal is overly complex, difficult to administer, and could be confusing for beneficiaries.**

As CMS notes, the vast majority (over 90%) of LIS beneficiaries do not elect to use an SEP in any given year, and, of those that do, the majority only do so once. The CMS stated goals are to reduce abuses related to chronic switching, not prevent switching altogether. As such, CMS has proposed creating several new and interconnected SEPs to ensure that appropriate switching is still allowed. While appropriate switching must be allowed, CMS does not indicate that a significant number of beneficiaries are engaged in chronic, yet still appropriate, switching. The proposed changes to SEPs appear to accommodate situations that generally do not exist. CMS should study the limited multiple SEP beneficiaries to examine what the root causes are and the proposed policy solutions.

In addition, the proposed interrelated SEP provisions are difficult to communicate to beneficiaries in a simple, easy-to-understand way. Rather than present a clear and precise set of alternatives, communications would need to describe a complex set of if/then statements, where various SEPs are dependent on prior SEPs, notification timelines, and risk category.

Given all the above, Humana believes a much simpler and more effective approach would be to limit LIS SEPs to no more than two in a given plan year. As CMS notes, this would effectively eliminate abuses tied to members who switched three or more times a year (27,000 beneficiaries in 2016). This two per-year limitation would be administratively more efficient. It would be a simpler and clearer process that could easily be communicated to beneficiaries, with little risk for confusion.

While CMS considered such an alternative, there were concerns that a two per-year limitation still allowed significant opportunities for mid-year changes and membership churning. While Humana does not dispute this, there is similar opportunity for member churn under CMS's proposal. For example, a beneficiary could be auto-assigned to a plan, and elect to utilize their SEP in February to enroll in a new plan. Subsequently, in May they may experience a change in their LIS status (or any other change triggering a currently existing SEP, such as moving), resulting in the use of another SEP. They would still have access to their one-time SEP, and choose to exercise that option in July. Then, in October, they would have the ability to change plans during the annual election period (AEP) for a January effective date. In this example, the beneficiary will have been enrolled in four different plans within one year. We do not believe that the membership churn risk in the CMS proposal is meaningfully different than creating a twice per year LIS SEP.

Given that all the various alternatives have their pros and cons, we propose that CMS adopt the simplest alternative, and limit LIS SEPs to no more than two in a given plan year. The impact of such a change should be closely monitored, and if CMS/plan sponsors find that there is continued abuse, or if certain beneficiaries face undue

hardships because of the changes, the LIS SEPs can be further altered to better achieve the stated goals.

II.A.11.b Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Background

CMS requests comments on whether the agency should consider implementing a demonstration project to test alternative approaches to Star Ratings designed to level the playing field between new entrants and renewing plans for a pre-determined period of time.

Comments: We have great respect for the complexities of managing MA contracts and we agree with and encourage innovation and continuous improvement of MAOs in order to better serve Medicare beneficiaries. However, we are concerned that a demonstration project explicitly aimed at benefitting new entrants, without regard to beneficiary impact, could lead to unintended adverse impacts on Medicare beneficiaries who enroll in potentially poor performing plans operated by MAOs with little program experience. Indeed, CMS's own analysis shows that on average, higher Star Ratings are associated with more experience in the MA and Part D programs and not a single 5-Star plan in 2017 had been in the program for less than 5 years.[19] CMS demonstrations have generally been required to either reduce spending without reducing the quality of care, or improve the quality of care without increasing spending. A Stars demonstration project would not increase quality, but it could increase overall program costs.

CMS proposes incorporating survey measures of physicians' experiences into the Star Rating system.

Comments: We fully support making changes to the program that could potentially increase plan participation, identify opportunities to improve benefit offerings to enrollees, and incentivize improved coordination between plans and providers. However, we do not support inclusion of a physician CAHPS-like survey because it would increase both plan and provider burden. For providers this would likely involve completing multiple surveys every year because their patients have different MA plans or PDPs. Indeed, a recent survey conducted by Humana and the American Academy of Family Physicians (AAFP) found that 61 percent of family physicians receive payment from seven or more health plans, and of that, 38 percent receive payment from 10 or more.[20]

CMS requests comments on whether the agency should explore additional adjustments to the Star Ratings measures and methodology to further account for unique geographic and provider market characteristics that affect performance (for example, rural geographies or monopolistic

[19] CMS 2017 Star Ratings available online at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-10-12.html

[20] See http://press.humana.com/press-release/study-finds-one-three-family-physicians-are-already-pursuing-value-based-payment

provider geographies), and the operational difficulties that plans could experience if such adjustments were adopted.

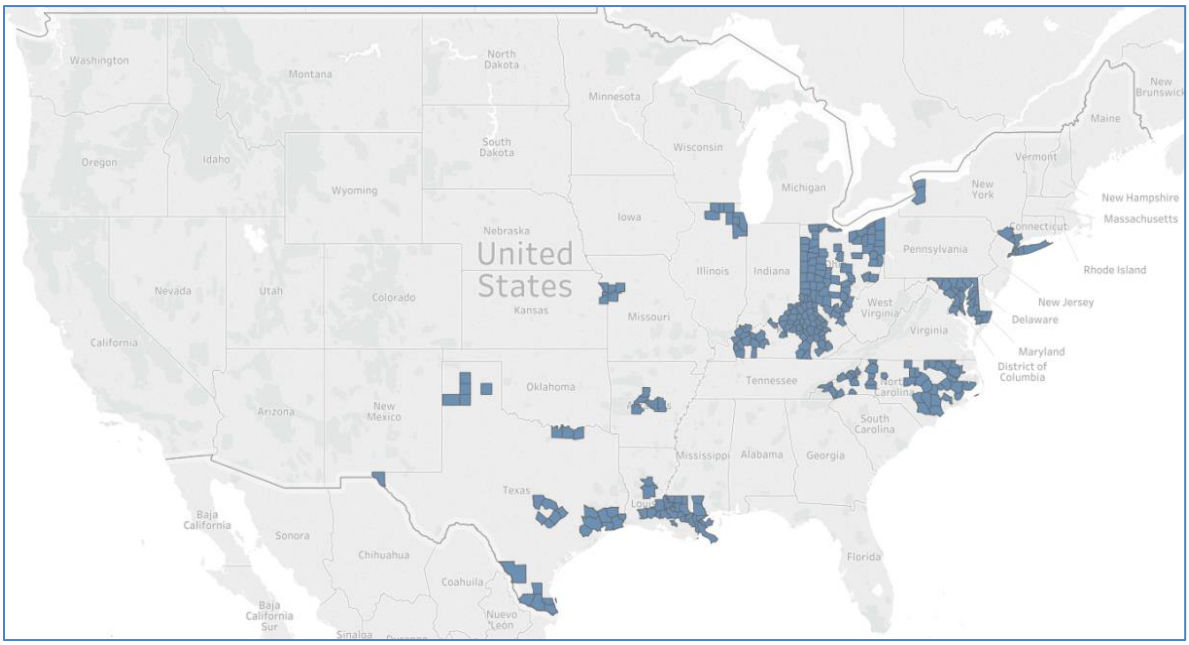
Comments: There has been considerable research on geographic variations in health care utilization, practice patterns, and prices, but most of these studies have focused on original fee-for-service (FFS) Medicare or the commercial health insurance market.[21] While the evidence base is somewhat limited, the available studies suggest a potential correlation between geographic factors and MA and Part D Star Ratings. For example, a 2015 study based on 2010 data found that geographic factors predicted a larger fraction of Star Ratings compared to socio-demographic factors.[22] A 2016 study sponsored by Pharmacy Quality Solutions, based on 2014 data, found statistically significant geographic variations in medication adherence measures for noninsulin diabetes medications, renin angiotensin receptor antagonists, statins, and variations in the use of high-risk medications in the elderly.[23] We also observe interesting patterns when mapping the counties with at least one low performing (less than 3 Stars) plan. All else being equal, we would expect to observe a relatively random and balance set of counties with at least one low performing plan. However, as illustrated by the map below, we see a clustering in a handful of states and counties. The collective evidence suggests that CMS should conduct a detailed examination of the potential geographic impacts on individual Stars measures and the summary score. We recommend CMS follow the same approach that was utilized to examine the effects of socioeconomic factors on Stars by engaging a reputable analytic contractor and conducting a transparent public discussion allowing for comments from stakeholders.

[21] Fisher ES, Wennberg JE. Health care quality, geographic variations, and the challenge of supply-sensitive care. Perspect Biol Med. 2003;46: 69–79. pmid:12582271. Goodney PP, Travis LL, Malenka D, Bronner KK, Lucas FL, Cronenwett JL, et al. Regional variation in carotid artery stenting and endarterectomy in the Medicare population. Circ Cardiovasc Qual Outcomes. 2010;3: 15–24. pmid:20123667. Congress of The United States, Congressional Budget Office. Geographic Variation in Health Care Spending [Internet]. 2008 Feb. Available: http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/89xx/doc8972/02-15-geoghealth.pdf. Fisher ES, Bynum JP, Skinner JS. Slowing the growth of health care costs—lessons from regional variation. N Engl J Med. 2009;360: 849–852. pmid:19246356. Reschovsky JD, Hadley J, O'Malley AJ, Landon BE. Geographic Variations in the Cost of Treating Condition-Specific Episodes of Care among Medicare Patients. Health Serv Res. 2014;49: 32–51. pmid:23829388

[22] Soria-Saucedo R, Xu P, Newsom J, Cabral H, Kazis LE (2016) The Role of Geography in the Assessment of Quality: Evidence from the Medicare Advantage Program. PLoS ONE 11(1): e0145656. https://doi.org/10.1371/journal.pone.0145656

[23] Desai V, Nau D, Conklin M, Heaton P (2016) Impact of Environmental Factors on Differences in Quality of Medication Use: An Insight for the Medicare Star Rating System. Journal of Managed Care Specialty Pharmacy, 2016 July; 22(7): 779-786. https://doi.org/10.18553/jmcp.2016.22.7.779

Map of 2018 Counties with a Less than 3-Star Plan[24]



II.A.12.c. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Basis, Purpose and Applicability of the Quality Star Ratings System

CMS is proposing to codify the current quality Star Ratings System uses, methodology, measures, and data collection beginning with the measurement periods in calendar year 2019.

Comments: We strongly support the CMS proposal to codify the Star Ratings System. The adoption of 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.

Despite the best intentions, the quest to measure performance has resulted in an overwhelming number of quality measures, many of which are inconsistent or duplicative, often not well aligned with health outcomes and not readily extracted from medical records. For example, in December 2016, Humana identified 1,116 quality metrics from 29 different data sources across the company. Working in collaboration with physician stakeholders, we identified 699 metrics that were duplicative or inconsistent.[25] Through these efforts, we were able to reduce the number of applicable quality metrics from 1,116 to 208 – an 81% reduction. This coordinated effort followed

[24] Map data sourced from the CMS CY2018 MA Landscape file

[25] Based on an internal Humana analysis. An article outlining our findings is scheduled for publication in an upcoming issue of the *American Journal of Medical Quality*.

the February 2016 introduction of Core Quality Measures by Humana, America's Health Insurance Plans (AHIP), leaders from the CMS and the National Quality Forum (NQF), as well as national physician organizations. This joint effort was aimed at facilitating the adoption of meaningful, efficient, payer-agnostic quality measures across the industry.

At the Health Care Payment Learning and Action Fall Summit, CMS Administrator Seema Verma stated that, "Clinicians and hospitals have to report an array of measures to different payers. There are many steps involved in submitting them, taking time away from patients. Moreover, it's not clear whether all of these measures are actually improving patient care." **We strongly support Administrator Verma's Meaningful Measure initiative, and we believe the proposed notice and comment process will provide an effective platform for taking steps to realize her vision.**

II.A.12.e. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Contract Ratings

CMS solicits comments on how to appropriately balance the improved precision associated with plan level reporting (relative to contract level reporting) with the negative consequences associated with an increase in the number of plans without adequate sample sizes for at least some measures.

Comments: The additional complexity and administrative burden for managing samples, data collection, and requirements at the plan level, far outweigh any incremental improvements in plan rating precision. This would be particularly true for plan sponsors with large enrollment contracts and several D-SNP plans within each contract.

CMS requests comments on whether some measure data should be reported at a higher level (parent organization versus contract) to ease and simplify reporting and still remain useful to incorporate into the Star Ratings. CMS is also exploring whether contract market area reporting is feasible when a contract covers a large geographic area.

Comments: We support simplification of measure reporting as it applies to centralized processes (e.g. call center measures). In order to facilitate this simplification, we recommend an HPMS module, similar to what is used for storing contract-level call center service numbers, to apply to the collection of information on other processes that are centralized among MA contracts. However, we believe measures that reflect geographical variations (e.g. HEDIS) should not be considered for reporting at a higher level than contract. This is because these measures generally reflect the performance of providers who are not providing care across all the contracts that a parent organization may have.

For SNP specific measures collected at the Plan Benefit Package (PBP) level, CMS proposes that the contract level score would be an enrollment-weighted mean of the PBP scores using enrollment in each PBP as reported as part of the measure specification.

Comments: Regional differences and nuances of continuous enrollment requirements for measures can lead to potential variation, from plan to plan, of the ratio of measure-eligible denominators to plan enrollment. We therefore believe the simplest and fairest approach for determining contract-level pass rates and Star scores is combining plan benefit package data by weighting each PBP's contribution to the final rate using administrative denominators. This is consistent with the current approach for the HEDIS Care for Older Adults (COA) measures.

II.A.12.f. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Contract Consolidations

CMS proposes to calculate the Star Ratings measure scores for a consolidated entity's first plan year based on enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except the survey-based and call center measures.

Comments: In order to ensure that plans have the information necessary to submit a fully informed plan bid, we recommend that CMS consider posting by year-end in HPMS or CMS.gov a worksheet with the exact enrollment and overall Star Rating values which CMS intends to use for determining quality bonus payment (QBP) ratings for consolidated contracts.

II.A.12.g. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Data Sources

CMS proposes to codify that MAOs and Part D plan sponsors are required to submit unbiased, accurate, and complete quality data.

Comments: The integrity of the Stars Rating system is contingent on the submission of accurate and reliable data by MAOs and Part D plan sponsors, which is why we strongly concur with CMS.

II.A.12.h. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Adding, Updating, and Removing Measures

CMS proposes to update and/or remove existing measures as warranted via the Advance Rate Notice and Call Letter. CMS further proposes that new measures and substantive updates to existing measures would be implemented via formal rulemaking.

Comments: As described in more detail above in our comments on Section II.A.12.c, we strongly support the CMS proposal to use rulemaking when adding new measures or when making substantive changes to existing measures. We also support the agency using the Advance Rate Notice and Call Letter as a vehicle for incorporating minor revisions in existing measures and for removing existing measures when there has been a change in clinical guidelines associated with the measure or reliability issues identified in advance of the measurement period.

For the 2021 Star Ratings, CMS proposes to adopt measures that encompass outcome, intermediate outcome, patient/consumer experience, access, process, and improvement measures. As new performance measures are developed and adopted, CMS proposes to initially incorporate them into the display page for at least two years. CMS may also keep a new measure on the display page for a longer period if the agency finds there are reliability or validity issues with the measure.

> **Comments: We support the CMS proposal to include a mix of different types of measures in the Star Ratings program, as well as the proposal to keep new measures on the display page for a minimum of two years.**

CMS proposes to codify a non-exhaustive list for identifying non-substantive updates that would be conveyed through the Advance Rate Notice and Call Letter rather than formal rulemaking.

> **Comments: We concur with the illustrative examples outlined in the proposed rule. We further recommend that CMS continue to solicit measure-level feedback in preliminary guidance to ensure CMS is receiving feedback from appropriate stakeholders prior to changes being implemented. Additionally, we recommend continuing to move the measures to the Display Page for at least one year.**

II.A.12.i. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Measure Set for Performance Periods Beginning on or after January 1, 2019

CMS proposes a variety of measures for performance periods beginning on or after January 1, 2019, which would be used when calculating 2021 Part C and Part D Star Ratings.

> **Comments: We generally support the proposed list of measures, but have included below a list of recommended technical adjustments.**

- **Reclassify Part D Statin Use in Persons with Diabetes (SUPD) -** Currently SUPD, similar to Part C Statin Therapy for Patients with Cardiovascular Disease (SPC), only requires a single fill of a statin medication for measure adherence. Furthermore, a second statin medication fill qualifies the enrollee for the 3-weighted Intermediate Outcome Part D Medication Adherence for Cholesterol (Statins) measure. SPC is currently a 1-weighted Process Measure. For the purposes of simplicity and consistency, we recommend classifying both SPC and SUPD as 1-weighted Process Measures.

- **Plan All-Cause Readmission –** In order to provide MAOs with greater visibility into plan performance, we recommend that CMS work with the National Committee for Quality Assurance (NCQA) to eliminate the calculation whereby a national average observed rate is multiplied by the observed to expected ratio of readmissions for Plan All-Cause Readmissions.

- **Medicare Plan Finder (MPF) Accuracy –** We recommend that CMS identify which of the two possible calculations will be included in the MPF Accuracy measure. CMS previously proposed to update the measure to include frequency and magnitude of prescription drug event (PDE) prices that exceed MPF information, beginning with the 2016 data, but reverted to the old measurement (only magnitude) with the 2018 Star Rating release.

- **Plan Makes Timely Decisions about Appeals –** 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 the Independent Review Entity (IRE) (including dismissals) per 10,000 members.

Humana further proposes that CMS create a new, fixed identification code for each measure that would be consistent year-over-year. The current three-character codes used to identify measures (e.g. C01, Breast Cancer Screening) may change every year as the measure set changes. A fixed identifier would make it easier for plans and enrollees to compare performance year-over-year. The new identifier could supplement, rather than supplant the current codes, so that CMS would still be able to publish the measure list with no "gaps" in the current code numbering.

II.A.12.j. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Improvement Measures

CMS proposes a new process for calculating the improvement measure score(s), and a special rule for any identified improvement measure for a contract that received a measure-level Star Rating of 5 in each of the two years examined, but whose associated measure score indicates a statistically significant decline in the time period.

Comments: We recognize that complex methods, used after the fact to determine the significance of improvement, can deter continuous improvement efforts. We also submit that depending on the level of measure performance, there is a natural concept of diminishing returns. **Humana therefore recommends a predictable gold standard be established for determining meaningful improvement as a set percentage reduction of a sub-optimal measure rate.** With this proposal, however, we believe that contracts performing above the 5-star threshold should have the measure counted as compliant for inclusion in the improvement measure calculation (a measure-level "hold harmless" criteria).

CMS proposes to determine the improvement measure score cut points using two separate clustering algorithms. Improvement measure scores of zero and above would use the clustering

algorithm to determine the cut points for the Star Rating levels of 3 and above. Improvement measure scores below zero would be clustered to determine the cut points for 1 and 2 stars. The Part D improvement measure thresholds for Medicare Advantage-Prescription Drug plans (MA-PDs) and PDPs would be reported separately.

> **Comments: We support the CMS proposal to use two separate clustering algorithms to determine cut points.**

CMS proposes to hold harmless sponsoring organizations that have 5-Star Ratings for both years on a measure used for the improvement measure calculation.

> **Comments: We support the CMS proposal to hold harmless sponsoring organizations that have 5-Star Ratings for both years on a measure used for the improvement measure calculation.**

II.A.12.k. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Data Integrity

CMS proposes to codify certain rules for the reduction of measure ratings when CMS identifies incomplete, inaccurate, or biased data that have an impact on the accuracy, impartiality, or completeness of data used for the impacted measures.

> **Comments: Humana supports the CMS proposal to reduce measure ratings when the agency identifies issues that impact the accuracy, impartiality or completeness of a plan's data. Humana also supports the proposal to reduce to 1 Star those HEDIS measures designated as Biased Rate (BR) based on an auditor's review of the data . Additionally, we agree with the CMS proposal to reduce a contract's rating to 1 Star, for measures related to Part C and D reporting requirements when the contract does not meet CMS's expectations for data validation of those reporting requirements. And finally, Humana supports the CMS proposal to use a scaled reduction approach in Star Ratings for appeal measures in both Part C and D, in lieu of the standard reduction to 1 Star.**

II.A.12.l. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Measure-Level Star Ratings

CMS is proposing to continue its existing policy of establishing cut points using clustering methodology for non-CAHPS measures and the use of relative distribution and significance testing for CAHPS measures.

> **Comments: We support the CMS proposal to continue establishing cut points using a clustering methodology for non-CAHPS measures. We also concur with the agency's proposal to utilize relative distribution and significance testing for CAHPS measures. However, we remain concerned regarding the substantial year-over-year variance in measure-level Star Rating cut points.** As illustrated in the most recent CMS *Trends in*

Part C and D Star Measure Ratings Cut Points, the majority of measure-level Star Ratings have been subject to significant year-over-year variation.[26]

In keeping with the continuous improvement of transparency in agency reporting in HPMS and cms.gov over the last several years, we recommend publishing the full data set used to calculate applicable cut points, including unrounded rates and denominators. This data would allow plans to more quickly and precisely identify areas for improvement.

CMS requests comments on pre-determined 4-star thresholds and suggestions for how to minimize generating Star Ratings that do not reflect a contract's "true" performance, or vice versa, creating "cliffs" in Star Ratings, and how to continue to create incentives for quality improvement.

Comments: We fully support the proposed methods outlined by CMS in the proposed rule, and believe the agency's proposals will improve the accuracy of a contract's "true" performance and eliminate the creation of "cliffs" in Star Ratings.

CMS is considering methodologies that would minimize year-to-year changes in cut points by setting the cut points as a moving average of the cut points from the two or three most recent years or setting caps on the degree to which a measure cut point could change from one year to the next. CMS invites comments on the proposed methodologies and recommendations for other ways to provide stability for cut points from year to year.

- **Comments: We support alternative approaches, including the methodology proposed by CMS, which are designed to reduce year over year variation in threshold changes, while still encouraging continuous improvement. We encourage CMS to work collaboratively with MAOs to test any new alternative approaches prior to implementation.**

II.A.12.m. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Hierarchical Structure of the Ratings

CMS proposes to continue using a hierarchical structure for Star Ratings.

Comments: We support the CMS proposal to continue using a hierarchical structure for Star Ratings.

[26] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2018-Cut-Point-Trend-2017_12_14.pdf

II.A.12.n. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Domain Star Ratings

CMS is proposing to continue using nine Part C and Part D domains and to use group measures for purposes of display on MPF. CMS further proposes that a contract must have Stars for at least 50 percent of the measures required to be reported for that domain for that contract type to have that domain rating calculated in order to have enough data to reflect the contract's performance on the specific dimension

Comments: We support the CMS proposal to continue using the existing policy for Domain Star Ratings.

II.A.12.0 and II.A.12.p. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Part C and D Summary Ratings and Overall Rating

CMS is proposing to continue calculating summary ratings in half-Star increments. MA-only and Part D standalone plans would receive a summary rating only for their Part C measures and Part D measures. CMS is also proposing to continue using half-Star increments for MA-PD plans.

Comments: We support the CMS proposal to continue the existing policy of calculating summary ratings on a 1-5 Star scale in half-Star increments.

II.A.12.q. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Measure Weights

CMS proposes to continue the current weighting of measures in the Part C and D Star Ratings program by assigning the highest weight (5) to improvement measures, followed by outcome and intermediate outcome measures (weight of 3), then by patient experience/complaints and access measures (weight of 1.5), and finally process measures (weight of 1). In addition, CMS is considering increasing the weight of the patient experience/complaints and access measures and seeks stakeholder feedback on this potential change

Comments: We support CMS continuing the current weighting of measures in the Part C and D Star Ratings program. We believe the current weighting strikes an appropriate balance between population health outcomes measures, patient experience measures, and process-based measures.

CMS proposes to continue assigning new measures a weight of 1 for their first year in the Star Ratings.

Comments: We support the CMS proposal to continue assigning new measures a weight of 1 during their first year in the program. We also support the measure weight being associated with the measure's weighting category in subsequent years.

CMS proposes to continue the existing exception to the general weighting rule for MA and Part D contracts that have service areas that are wholly located in Puerto Rico, in order to reflect the unique challenges related to medication adherence in Puerto Rico resulting from the lack of a

LIS. More specifically, CMS proposes to reduce the weights for the adherence measures to 0 for the summary and overall rating calculations and to maintain the weight of 3 for the adherence measures for the improvement measure calculations for contracts that solely serve the population of beneficiaries in Puerto Rico.

Comments: We support the CMS proposal to maintain the existing exception to general weighting for plans with service areas wholly located in Puerto Rico.

II.A.12.r. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Application of the Improvement Measure Scores

CMS proposes to maintain the existing hold harmless provision for the inclusion or exclusion of the improvement measure(s) for highly-rated contracts' highest ratings.

Comments: We support the CMS proposal to continue to using the hold harmless provision for highly-rated contracts' highest ratings.

II.A.12.s. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Reward Factor

CMS proposes the continuation of existing policy and methodology to use a reward factor to reward contracts with consistently high and stable performance over time.

Comments: We support the CMS proposal to continue using the reward factor to reward consistently high performing plans.

II.A.12.t. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Categorical Adjustment Index (CAI)

CMS proposes to continue to using the CAI to adjust for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low-income subsidy and/or are dual eligible and/or have disability status.

Comments: We support the CMS proposal to continue using CAI and look forward to receiving additional information through the Advance Rate Notice and Call Letter process. Additionally, we support CMS continuing to apply additional adjustments for contracts in Puerto Rico.

II.A.12.u. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – High and Low Performing Icons

CMS proposes to continue assigning a high performing icon to an MA-only contract for achieving a 5-star Part C summary rating, a PDP contract for a 5-star Part D summary rating, and an MA-PD contract for a 5-Star overall rating. Conversely, a contract would receive a low performing icon when they have a summary rating lower than 3 Stars, in either Part C or Part D, for three consecutive years. Lastly, CMS proposes to continue disabling the MPF online enrollment function for Medicare health and prescription drug plans with the low-performing icon.

Comments: We support the CMS decision to continue assigning the high performing icon for health plans that achieve a 5-Star Rating and conversely, a low-performing icon when a health plan achieves a Star Rating below 3 Stars for three consecutive years. Humana agrees with the need to protect beneficiaries from enrolling in plans that continuously perform below average, and thus we support disabling the MPF for these contracts.

II.A.12.v. Medicare Advantage and Part D Prescription Drug Program Quality Rating System – Plan Preview of Star Ratings

CMS proposes to continue offering plan preview periods before Star Ratings are released.

Comments: We support the CMS proposal to continue the plan preview periods and appreciate the enhancements CMS continues to make to the preview periods. Moving forward, we request that CMS include full data sets that would allow plans to effectively analyze the measures and determine cuts points. Specifically, we request CMS release the Part C and Part D Improvement Measure details (i.e., the improvement measure calculation emulation spreadsheets) for all contracts, including unrounded rates, significance calculations, and other data.

III.A.12. Any Willing Pharmacy Standard Terms & Conditions and Better Define Pharmacy Types (§§ 423.100, 423.505)

In the proposed rule, CMS intends to clarify that the Part D any willing pharmacy (AWP) requirement applies to all pharmacies, regardless of how they are organized, as one or more lines of pharmacy business. CMS notes that, if finalized, the requirements would apply to all pharmacies whether they fit into traditional pharmacy classification or have unique or innovative business or care delivery models. Second, CMS proposes to revise the definition of retail pharmacy and define mail-order pharmacy. Third, CMS proposes to clarify regulatory requirements for what constitutes "reasonable and relevant" Part D standard contract terms and conditions. Lastly, CMS proposes to codify existing guidance regarding when a pharmacy must be provided with a PDP sponsor's standard terms and conditions.

Comments: Humana has concerns with this proposal. Section 1860D-4(b)(1)(A) of the Social Security Act states that "[a] prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan." (42 U.S.C. § 1395w-104(b)(1)(A)). CMS further interpreted the meaning of the AWP provision in a Part D final rule issued January 28, 2005, stating that PDP plans must "offer pharmacies reasonable and relevant standard terms and conditions for network participation." CMS now proposes extending a single standard terms and conditions requirement to all pharmacies, regardless of their model(s) or type of classification. The AWP statutory provision does not preclude a plan from negotiating, through standard terms and conditions, that a network pharmacy be proficient in a specific pharmacy practice model, based on terms and conditions that may include quality standards, state licensure, or accreditation. A pharmacy's practice of unique or innovative business or

care delivery models does not authorize a pharmacy to be free of exposure to terms and conditions that require meeting industry quality standards associated with those pharmacy models. The proposal would prevent the negotiating of contract agreements requiring the achievement of quality standards developed by national accreditation bodies for practicing a discrete type of pharmacy profession.

Specifically, the proposal would require sponsors to contract with any pharmacy that agrees to meet the terms and conditions, whether or not it can be shown that the pharmacy meets the quality standards of a practice model. This would eviscerate a plan's ability to require that quality pharmacy services be provided to beneficiaries and limits negotiating power that seeks to extend higher levels of service and quality care that would be required of pharmacies that are currently in a plan's network. Further, it subjugates standard terms and conditions to be singularly focused on reimbursement rates as opposed to quality, setting up a race to the bottom for pharmacy reimbursement in exchange for network participation. This will not help Medicare beneficiaries, and it will increase costs. Indeed, one study found the effect of any willing provider/ freedom of choice regulations is associated with cost increases of at least 3 percent.[27]

- <u>The Proposal Institutes a Price Structure</u>
  Section 42 U.S.C. § 1395w-111(i) stipulates that CMS may not "require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs." Humana believes that this proposal would violate the prohibition on instituting a pricing structure in that it seeks to define both a retail and mail order pharmacy based on cost sharing terms. Beneficiary cost sharing is, in fact, reimbursement to a pharmacy for the beneficiary portion of the negotiated price for a covered Part D drug. As such, we believe CMS is inadvertently dictating a pricing structure for the reimbursement to a pharmacy, because the determination of pharmacy status dictates a pricing structure in the form of cost sharing.

- <u>Any Willing Pharmacy Required for All Pharmacy Business Models</u>
  CMS states that it is inappropriate to decline to permit network participation by a pharmacy offering multiple lines of business. While Humana agrees that declining wholesale network participation exclusively due to multiple pharmacy service offerings is inappropriate, plans should be permitted to grant applying pharmacies entry into the network for services based on the pharmacy's ability to comply with the terms and conditions specific to each service model individually. For example, if a pharmacy offers retail and home infusion services and is able to agree to and demonstrate compliance with the plan's retail terms and conditions, but not the plan's home infusion terms and conditions, the pharmacy should be granted access to the retail network only and not the home infusion network until such time that the pharmacy is willing and able to

[27] The Effect of Any Willing Provider and Freedom of Choice Laws on Prescription Drug Expenditures, available online at http://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=1437&context=faculty_scholarship

comply with the home infusion pharmacy terms and condition requirements. We recommend that CMS clarify in the final rule that nothing precludes a plan from structuring standard terms and conditions addressing a particular pharmacy practice model or models and applying those terms and conditions to pharmacies providing multiple pharmacy services.

- The Proposed Definition of Mail Order Pharmacy

  Humana believes that the proposed definition of mail order pharmacy is overly narrow and excludes all pharmacies that generally service customers through mail delivery as their primary course of business, except those that are closed door pharmacies that dispense extended day's supplies of covered Part D drugs. For example, specialty pharmacies and many compounding pharmacies are generally not open to the public, or may require an affiliation with a medical provider. Therefore, they are not included in the proposed modification to the definition of retail pharmacy, yet typically do not dispense extended day supplies and would therefore be excluded from the proposed new definition of mail order pharmacy.

  CMS proposes to define mail-order pharmacy in § 423.100 "as a licensed pharmacy that dispenses and delivers extended days" supplies of covered Part D drugs via common carrier at mail-order cost-sharing." Humana encourages CMS to modify this proposed definition of mail-order pharmacy to "a pharmacy that is licensed in each state, territory, or the District of Columbia into which it dispenses and delivers covered Part D drugs via common carrier." We believe it is inappropriate to define a mail order pharmacy based on a cost sharing benefit design. Additionally, our proposed definition of mail order pharmacy ensures that pharmacies are licensed in all of the states in which they are practicing, by the applicable State Boards of Pharmacy charged with oversight of the practice of pharmacy by pharmacists and pharmacies impacting the citizens of their respective states.

- The Proposed Modification to the Definition of Retail Pharmacy

  CMS proposes to amend the definition of retail pharmacy in § 423.100 to read "any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy." As discussed previously, while we believe it is inappropriate to define a retail pharmacy based on a cost sharing benefit design, Humana supports the proposed definition in that it requires a retail pharmacy to dispense prescription drugs to "the walk-in general public." However, we are concerned that "the walk-in general public" will be literally interpreted by some pharmacies as simply having a front door through which the general public **could** enter. Humana has identified many pharmacies that may claim to be a retail pharmacy --due to the fact they have a door for "walk-in general public" to enter. However, upon inspection, they were operating within an industrial park with minimal public signage and were dispensing a *de minimis* percentage of prescriptions to members at the pharmacy

counter. They were, in effect, operating as a national mail order pharmacy rather than a retail pharmacy. However, CMS's proposed retail pharmacy definition would classify these pharmacies as a retail pharmacy subject to the same standard terms and condition as a local traditional retail pharmacy that fills 100% of patient prescriptions at the counter. Allowing plans to offer terms and conditions that are relevant to the actual business model of the pharmacy is the most critical tool that plans have to ensure pharmacies are held to quality standards and to minimize plan and government exposure to fraud, waste, and abuse.

Humana suggests that CMS revise the definition of retail pharmacy to be consistent with the definitions adopted by Medicaid at § 447.504(a): "an independent, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the state and dispenses medication to the walk-in general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to the patients primarily through the mail, nursing home pharmacies, long-term pharmacies, government pharmacies or pharmacy benefit managers."

Timing and Effective Date

Given the late release of this notice of proposed rulemaking (NPRM), we believe it is very unlikely that the final rule will be released in time to be operationalized in the Advance Notice and Draft Call Letter for CY2019. Moreover, plans are already in CY 2019 contract negotiations based upon current regulations. Accordingly, we recommend a 2020 effective date for the final regulatory provisions in this section.

II.A.13. Changes to the Days' Supply Required by the Part D Transition Process (§ 423.120 (b)(3)(iii))

CMS's is proposing to shorten the required transition days' supply in the long-term care LTC setting to the same supply currently required in the outpatient setting. CMS is also proposing a technical change to the current required days' transition supply in the outpatient setting to be "a month's supply."

Comments: **Humana is pleased that CMS is willing to modify the transition rules which will eliminate additional drug waste and costs by no longer requiring a longer transition days' supply in the LTC setting and by proposing the transition days' supply be the same as in the outpatient setting.** This change will require minimal information technology effort by plans to implement by the proposed date. Humana and other PDP sponsors are engaged in ongoing efforts to combat waste in the pharmacy setting and to lower beneficiary costs and, as such, we support the proposed changes to transition supply requirements.

II.A.14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 422.100, 423.120, and 423.128)

The proposed provisions would provide more formulary flexibility by, for instance, permitting Part D sponsors to immediately substitute newly-released equivalent generics for brand name

drugs at the same or lower cost-sharing, if they meet revised requirements, including generally advising enrollees beforehand that such changes can occur without a specific advance notice and later providing information to affected enrollees about any specific generic substitutions that occur.

> **Comments: Humana supports this proposal allowing increased flexibility for sponsors to implement midyear formulary changes.** Permitting expedited midyear formulary changes will allow PDP sponsors to act more quickly on newly available clinical information and to respond more timely and effectively to changing market dynamics. Additionally, as MedPAC notes in its *June 2016 Report to Congress*, allowing plan sponsors this flexibility will give them more leverage in price negotiations with drug manufacturers, "potentially leading to lower enrollee premiums and cost sharing."[28] We believe that this proposal strikes the appropriate balance between beneficiary protections and plan flexibility and that it should be finalized. We recommend that CMS also permit the immediate substitution of newly-released interchangeable follow-on biological products, approved under section 351(k) pathway, for the brand name innovator drugs at the same or lower cost-sharing, if revised notice requirements are met.

II.A.15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic Cost Sharing and LIS Cost Sharing

This provision would further encourage the use of lower-cost alternatives by classifying follow-on biological products as generics for the purposes of cost-sharing for Part D enrollees who do not receive the LIS and are in the catastrophic portion of the benefit, and for LIS Part D enrollees throughout all phases of the benefit.

> **Comments: We support CMS revising the definition of generic drug at § 423.4 to include follow-on biological products approved under the section 351(k) pathway for the purpose of non-LIS catastrophic cost sharing and LIS cost sharing.** This will result in cost savings for enrollees and for plans. It is important to note that a change in statute is needed requiring biosimilar manufacturers to be subject to the coverage gap discount program (as currently is required of formulary biologic products) in order for non-LIS enrollees to be subject to lower cost sharing for biosimilars in the coverage gap. We urge CMS to advocate for the necessary statutory changes when this proposal is finalized.

II.A.16. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences (§ 423.265)

For the 2019 plan year, CMS has proposed to eliminate meaningful difference requirements between Sponsors' first and second EA offerings, while retaining such requirements between sponsors' basic offerings and enhanced alternative offering(s). In addition, CMS is seeking

[28] June 2016 Report to the Congress: Medicare and the Health Care Delivery System, page 194-195

comment on potential alternative methods of calculating/defining meaningful difference that better align with beneficiary preferences.

Comments: Humana strongly supports the CMS proposal to eliminate meaningful difference requirements between EA plans. We believe this will allow sponsors to better design plans around current and future beneficiary needs, as opposed to designing plans to meet actuarial calculations. Furthermore, it will eliminate unneeded disruption and provide more plan stability to beneficiaries currently enrolled in second EA plans, as sponsors will not be forced to adjust benefits to comply with changing requirements. Lastly, we believe this will result in a greater number of competitive plan offerings in the market, providing more choice and increased value to beneficiaries.

Though CMS has proposed to eliminate meaningful difference requirements between EA plans, CMS intends to maintain similar requirements between basic and EA offerings to ensure there is meaningful value for beneficiaries given the supplemental Part D premium associated with the enhanced plans. **While Humana understands and supports the intent of providing meaningful value to beneficiaries in exchange for supplemental premium, it is important that CMS set a consistent and reasonable OOPC differential that does not change from year to year.**

There is no indication that beneficiaries change their perception of meaningful difference from year-to-year, and even if they did, they would likely not base their preferences on the prior year's distribution of OOPC values across plans. A less disruptive way to manage meaningful difference thresholds would be to simply define an appropriate threshold that remains constant (for example, CMS could establish the current $20 threshold as the value going forward). This would afford sponsors more predictability and reduce unnecessary changes, while still ensuring beneficiaries receive meaningful value.

Humana is also supportive of CMS reexamining what methodology should be used in determining meaningful difference. As we have stated in previous comment letters, beneficiaries may consider a multitude of other factors such as premium, pharmacy network, preferred pharmacy networks, Star Ratings, copay versus coinsurance, customer service and digital experiences, and brand perceptions, among key characteristics of meaningful difference between PDPs. While these factors are important to beneficiaries, they are, unfortunately, more difficult to objectively measure through actuarial calculations. As such, Humana does not believe a formulaic approach is the optimal way to determine meaningful difference, and that consumer research is needed to determine what beneficiaries may or may not consider meaningfully different. CMS should partner with plan sponsors to conduct research to better understand beneficiary perceptions of value and meaningful difference. We also believe such research should focus on the perceptions and needs of particular market niches in Medicare, as the existing methodology (and the subsequent existing research) has focused on the aggregate Medicare market.

In conjunction with beneficiary research, CMS should also consider allowing sponsors to offer more than two EA plans in a given PDP region, particularly in cases where it is determined that specific market niches exist. Current limitations on the number of plan offerings have generally caused sponsors to focus on plans that appeal to the broadest consumer segment in order to attract the largest numbers of beneficiaries. Unfortunately, this causes smaller segments of the population that may have specific needs to be ignored, as sponsors are not willing to sacrifice growth by abandoning products that appeal to the broader population.

Though Humana believes that an expansion of EA offerings would provide significant value to beneficiaries and the Part D program, we acknowledge that there is little, if any, research or understanding of how to tailor products to smaller, more targeted populations (as past research has generally been constrained by the existing limitations on plan offerings). As such, we believe CMS should closely monitor any expansion of the number of EA plan offerings to ensure that additional value is being created in the market.

II.A.17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions at the Point of Sale (POS)

CMS solicited comment, as a Request for Information (RFI), on requiring sponsors to include at least a minimum percentage of manufacturer rebates received for a covered Part D drug in the drug's negotiated price at the POS. CMS stated that feedback received will be used for consideration in future rulemaking on this topic. CMS notes that under current law, plan sponsors are not explicitly required to reflect price concessions from drug manufacturers in the negotiated price at POS; rather, sponsors can choose whether to reflect such price concessions at the POS.

CMS states their acknowledgement that the existing benefit of manufacturer price concessions reported as direct and indirect remuneration (DIR) is lower beneficiary premiums. However, CMS is concerned with the negative impact this has on beneficiary drug access due to higher cost sharing. They postulate that under current rules, plans "may have weak incentives, and in some cases even no incentive to lower prices at POS or to choose lower net cost alternatives." As a result, CMS believes that the true price of a drug is not available to beneficiaries at POS nor is it reflected on MPF. CMS sets out scenarios as to how this "could result in bids that are not comparable and in premiums that are not valid indicators of relative plan efficiency."

CMS seeks comment on how to most effectively design a policy to require pass-through at POS of a minimum percentage of weighted average rebates in order to mitigate effects of manufacturer prices concession reported as DIR. CMS acknowledges this would result in larger premium increases for all beneficiaries and also may result in weaker incentives for plans to participate in Part D. CMS specifically seeks comment on how to do this without increasing government costs or reducing manufacturer payments under the Coverage Gap Discount Program (CGDP).

Comments: While improvements can always be made, Humana thinks it is important to first acknowledge that much is going right in Medicare Part D. A quick summary list of positive developments includes:

- Flat average enrollment-weighted Part D monthly premiums from CY2012 to current.[29]
- A downward trend in Part D plan administrative costs and margin as a percentage of total expenditures from CY2010 to current.[30]
- The overwhelming majority of beneficiaries are satisfied with their PDP and access to prescription drugs.[31]
- Flat trends in Part D Direct Subsidy payments to plans.[32]
- The growth in per beneficiary Part D spending is back down after Hepatitis C drugs caused a spike that started in CY2014.[33]

Regulating Part D sponsors and pharmacy benefit managers (PBMs) alone only gives leverage to brand drug manufacturers. The Part D prescription drug supply chain begins with the manufacturer and ends with the dispensing pharmacy. In between, prescribers, wholesalers/distributers, and the Part D sponsor are involved in the process. President Trump could not have been more clear about the role of manufacturers in high drugs prices when he stated that the "***drug companies, frankly, are getting away with murder, and we want to bring our prices down to what other countries are paying, or at least close and let the other countries pay more. Because they're setting such low prices that we're actually subsidizing other countries, and that's just not going to happen anymore***."[34] However, the regulatory framework CMS is potentially considering would only apply oversight and requirements on the Part D sponsor and its PBM. This approach is unlikely to reduce unit prices or total costs, as it only gives more negotiating leverage to manufacturers and dispensing pharmacies. We acknowledge that CMS alone does not have jurisdiction over all of the players, but if the Administration desires to reduce drug prices through direct government action, it can only be effective by regulating **all** the participants. Regulating plan sponsors alone will only increase premiums, as CMS has acknowledged, and create unforeseen market distortions.

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[29] MedPAC Report to Congress: Medicare Payment Policy, March 2017

[30] 2017 Medicare Trustees Report

[31] 2017 CMS Stars Report Card Master Table. Notes: "Rating of Drug Plan" This case-mix adjusted measure is used to assess members' overall view of their prescription drug plan. The Consumer Assessment of Healthcare Providers and Systems (CAHPS) score uses the mean of the distribution of responses converted to a scale from 0 to 100. The score shown is the percentage of the best possible score each contract earned. "Getting Needed Prescription Drugs" Percent of the best possible score the plan earned on how easy it is for members to get the prescription drugs they need using the plan.

[32] MedPAC Report to Congress: Medicare Payment Policy, March 2017

[33] 2017 Annual Report of the Medicare Board of Trustees

[34] Remarks from President Trump available online at https://www.whitehouse.gov/briefings-statements/remarks-president-trump-cabinet-meeting-4/

We see no policy purpose in giving more leverage to brand drug manufacturers in their negotiations with Part D sponsors. By any measure, the drug manufacturing industry is doing exceedingly well. Indeed, a recent study by the Government Accountability Office (GAO) found that about 67 percent of all drug companies saw an increase in their annual average profit margins from 2006 to 2015 and among the largest 25 companies, annual average profit margins were between 15 and 20 percent.[35] Similarly, industry data compiled by the Stern School of Business at New York University finds the profit margins of biotechnology and traditional drug manufacturers are higher than anyone else in the healthcare sector or most other industries for that matter.[36] From a gross profit perspective, Fortune 500's "Most Profitable List" does not contain any Part D sponsors, but it does list Johnson & Johnson and Gilead Sciences.[37] **As CMS's own analysis demonstrates, the proposed POS rebate would produce a windfall for brand drug manufacturers by reducing their coverage gap discount liabilities between 7 to 20 percent.[38]**

Implementing a POS Rebate Rule is inconsistent with the Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs. On January 30, 2017, President Trump issued an Executive Order directing agencies "to be prudent and financially responsible in the expenditure of funds, from both public and private sources. In addition to the management of the direct expenditure of taxpayer dollars through the budgeting process, it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations."[39] Implementing POS rebates would increase both plan and CMS program costs.

CMS does not provide cost estimates for this RFI concept in the proposed rule or in the "Supporting Statement Medicare Advantage Program and Supporting Regulations" document.[40] However, the CGDP represents a historical program similar to a POS rebate. At a high level, the Part D coverage gap discount is a legislatively mandated POS rebate, but for a defined percentage and for a non-LIS population only. In the April 15, 2011, rule implementing the CGDP, CMS estimated a one-time plan implementation cost of $50.4 million and 12,000 burden hours.[41] For subsequent years CMS estimated the total annual cost would be $1.05 million and 250 burden hours per claims processor. While CMS does not report administrative spending by program, a review of CMS

[35] GAO, "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals," available online at https://www.gao.gov/assets/690/688472.pdf
[36] Data available online at http://people.stern.nyu.edu/adamodar/New_Home_Page/data.html
[37] Fortune 500 Most Profitable List, available online at http://fortune.com/fortune500/list/filtered?sortBy=profits&first500
[38] 82 FR 56425
[39] Executive Order on Reducing Regulation and Controlling Regulatory Costs available online at https://www.whitehouse.gov/presidential-actions/presidential-executive-order-reducing-regulation-controlling-regulatory-costs/
[40] CMS-R-267, OMB 0938-0753
[41] 76 Federal Register 21545

budget and contract documents indicates that at least $1 million is spent per annum on CGDP activities.[42] Since the CGDP represents a smaller and less complicated version of a POS rebate, it is reasonable to assume the costs outlined above would represent a very low-end estimate of the administrative burden and costs for a full Part D POS rebate regulation. Adding these burdens and costs without a Congressional mandate is clearly inconsistent with the Executive Order on Reducing Regulation and Controlling Regulatory Costs.

The reasoning behind the call for POS rebates lacks appropriate context. Among the core presented reasons for considering a POS rebate policy are: 1) beneficiaries may see lower premiums, but pay higher cost sharing; 2) the PDE reported negotiated price is rendered less transparent and quality of information available to consumers is less conducive to producing efficient choices; and 3) the rebates received above the bid projection contribute primarily to plan profits, not lower premiums. We address the broader context for each of these below:

1. **All health insurance is a balance between cost sharing and premiums** – assuming budget neutrality, any reduction in cost sharing will increase premiums. As the Congressional Budget Office (CBO) aptly notes, "changes in cost-sharing requirements primarily affect premiums" and reductions in cost sharing increase overall utilization and thus costs.[43] This is driven primarily by two factors. First, the cost sharing liability of the higher utilizers is spread among all the enrollees as premium. Second, the reduced cost sharing induces additional utilization.
2. **Part D plans are more transparent than all others in the prescription drug supply chain** – through the submission of bids, PDEs, and DIR reports for the Part D payment reconciliation, PDP sponsors provide more data to CMS than any other part of the prescription drug supply chain. Moreover, certain sponsor pricing data is publicly available to consumers via the Medicare Plan Compare tool. Drug manufacturers, wholesalers, and pharmacies do not report any comparable data to CMS or publicly.
3. **DIR variances can go both ways and protections already exist**– CMS expresses concern that Part D sponsors are estimating less DIR in their bids than they actually received. However, Humana has experienced variances in both directions for expected versus actual rebates as a proportion of total spend. The drivers of actual rebates being higher than expected are usually attributable to either new rebate agreements from new drug indications mid-year and/or much higher than expected enrollment leading to higher volume-based price concessions. There are several existing mechanisms to prevent abuse in this area. For example, underbidding DIR causes premiums

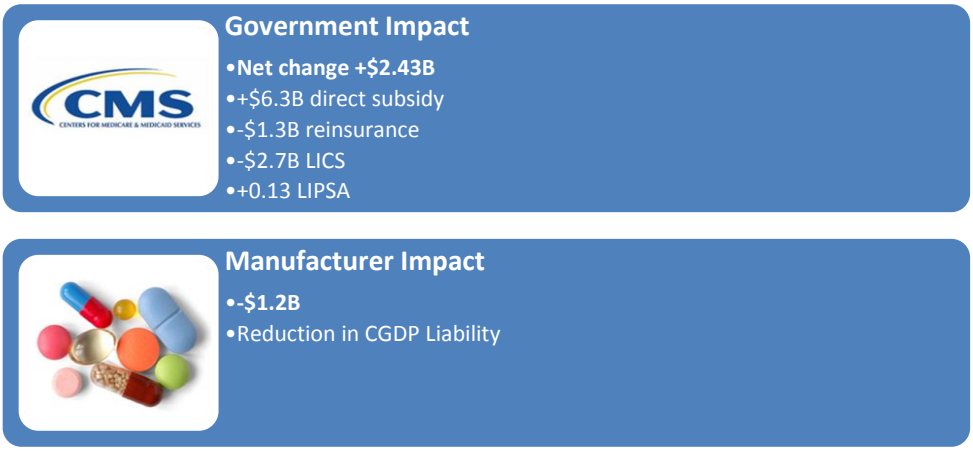
[42] Centers for Medicare & Medicaid Services, Justification of Estimates for Appropriations Committees, CY2018 and CMS contract awards data regarding Palmetto and other contractors involved with the CGDP available online at www.usaspending.gov

[43] CBO, "Key Issues in Analyzing Major Health Insurance Proposals," December 2008.

to be higher (less competitive) and could move a plan over the low income benchmark. Moreover, the minimum medical loss ratio penalties and the Office of the Actuary's profit tests regulate additional profits.

Applying POS rebates will increase costs and relatively few plan members would benefit. CMS's own analysis finds estimates that the POS rebate proposal would increase premiums from 4 to 11 percent and total government costs from 2 to 6 percent.[44] Humana has conducted extensive analysis utilizing data from its most recent full calendar year Part D program experience (see Figure below) to evaluate a policy that would require manufacturer negotiated price concessions to be reported on the PDE at the POS.[45] Humana unequivocally determined that such a policy would produce net increased government expenditures in the form of increased direct subsidy payments and higher low income premium subsidies. Our analysis confirms a savings to the government composed of a reduction in individual reinsurance payments and low income cost sharing that is cannibalized by the aforementioned increase in expenditures. The analysis also confirms that drug manufacturers will always have a reduction in CGDP liability by applying rebates at the POS. There is a proportional effect to the cost and savings such that there is no scenario in which rebates passed through at the POS, whether at a 100% pass through rate or something less, could result in a decreased consumption of scarce Medicare Trust Fund resources while also not reducing manufacturer CGDP liability. In other words, we see no combination of proposals where implementing POS rebates could be accomplished without increasing government costs and reducing manufacturer CGDP payments.

2016 Annual Program Cost/Savings (in Billions) - Moving Manufacturer Price DIR to POS[46]



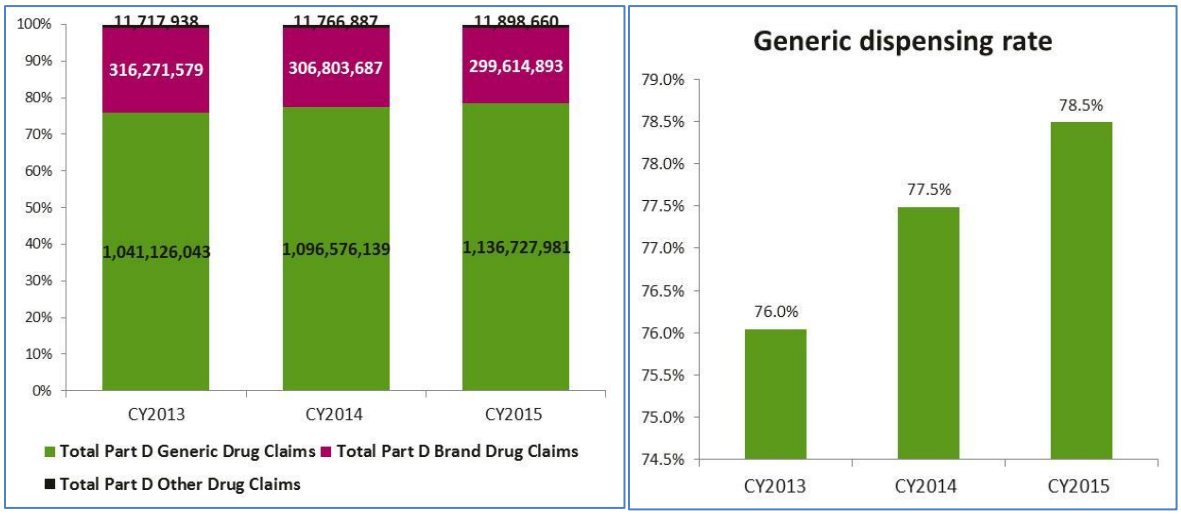
[44] 76 Federal Register 21545

[45] Full calendar year 2016 Humana Part D experience was utilized to accurately evaluate the impact to all Part D payment components.

[46] Cost and savings reflect RFI POS rebate policy applied to 2016 Humana experience at 100% rebate pass through. 2016 Humana Medicare Advantage and PDP data and CMS MA and PDP Monthly Contract Report (April 2017)

Part D has a very high generic dispensing rate and plans do not receive rebates on generics. It is also important to note that generic drugs account for the vast majority of Part D program utilization and now exceed 80% in the Part D program, creating a diminishing opportunity for rebates applied at the POS, which are only applicable to rebated brand name drugs. In CY 2016, low-cost generic drugs accounted for 87% of overall prescription drug utilization for Humana. Despite accounting for the vast majority of utilization, these drugs only contributed to 24% of total drug costs in 2016. Generic drug competition has contributed to consumer affordability and as a result limits the utility of any POS rebate policy to reduce cost sharing for the super majority of Part D members. To demonstrate, we calculated the frequency distribution of annual cost sharing savings and the associated percentage of Humana membership that would have received the annual cost sharing savings if rebates at the POS were required during the 2016 plan year (see table below). Of note, these are cost sharing savings only and do not include the 2016 annual premium increases that would have applied to all members under a POS rebate policy.

Trends in Brand vs. Generic Utilization in Part D[47]



Seventy-one percent of Humana's membership would receive $0 in cost sharing reduction, 19% would receive $100 or less in annual cost sharing reductions, and only 10% of membership would receive more than $100 in annual cost sharing savings. Of note, varying the percentage of rebate pass-through at the POS does not affect the percentage of members that would receive annual cost sharing savings. Varying the

[47] Part D Prescriber PUF Grand Totals and Overall Averages, Calendar Year 2013 ; CMS PartD_Prescriber_PUF_Grand_Totals_14 File; CMS Part D Prescriber PUF Grand Totals and Overall Averages, Calendar Year 2015 ; https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html. Notes: A drug is classified as "generic" using the FDA approval category of Abbreviated New Drug Application (ANDA). A drug is classified as "brand" using the Food and Drug Administration (FDA) approval category of New Drug Application (NDA), NDA authorized generic, or Biologic License Application (BLA). A drug is classified as "other" using any FDA approval categories not included in the brand or generic definitions.

pass-through rebate amount at the POS only proportionally reduces the magnitude of the nominal cost sharing savings. For example, with a 50% rebate pass through at the POS, 19% of members would receive $50 or less in annual cost sharing reductions.

Frequency Distribution of Annual Member Cost Sharing Reductions with POS Rebates[48]

Annual Sum of Cost Sharing Savings	Percentage of Membership
$0	71.3%
<$20	8.3%
$21-$40	4.3%
$41-$60	3.0%
$61-$80	2.0%
$81-$100	1.4%
$101-$1,000	9.4%
>$1,000	0.2%

Weighted average of rebates method will not increase transparency. CMS requested comment on requiring, through future rulemaking, Part D sponsors to include in the negotiated price reported to CMS for a covered Part D drug, a specified minimum percentage of the cost-weighted average of rebates provided by drug manufacturers for covered Part D drugs in the same therapeutic category or class. As outlined in the RFI background, CMS notes a lack of drug price transparency for consumers, both at the POS and on MPF, to efficiently make purchasing decisions that minimize out-of-pocket costs. CMS states that the proposals in the RFI would improve price transparency over the status quo, especially at the drug category or class level, and improve market competition and efficiency under Part D as a result.

Our analysis of applying a weighted average rebate to rebated drugs within a category or class demonstrated that this methodology would create "artificial drug price transparency" which further obscures consumer purchasing decisions and is counter to CMS's goal of improving price transparency. This phenomenon is illustrated in the table below with a hypothetical drug category/class analysis with a calculated average rebate of 16%. False price transparency results from drugs with higher negotiated rebates artificially lowering the negotiated price for drugs with lower negotiated rebates. False price transparency inadvertently distorts consumer buying signals because drugs with higher negotiated rebates subsidize the cost of drugs with lower negotiated rebates. Drug A in Table 2 exemplifies this subsidization with the 16% average rebate creating a price point buying signal that is $110 lower than the actual net price. The converse is also the case, illustrated by Drug B, where the consumer buying signal is distorted because drugs with negotiated rebates that are higher than the average create a price point that is $399 higher than the actual net price. These distorted buying signals do

[48] Humana 2016 Part D program experience modeled under a 100% rebate pass through scenario.

not improve drug price transparency over the status quo for the consumer. The difference in the negotiated price (a) between Drug A and Drug B is $200 while the difference in the POS rebate price (d) of Drug A and B is $168. POS rebates only artificially diminish the relative price difference between the two competing drugs, as seen by the consumer.

Illustrating "Artificial Drug Price Transparency" Average of Rebates Method

Drug	(a) Negotiated Price	(b) Plan Negotiated Rebate	(c) Actual Net Price [a- (a*b)]	(d) Negotiated Price with Weighted average POS rebate of 16% [a-(a*0.16)]	Artificial Price Transparency [d-c]
Drug A	$2,000	0.1	$1,800	$1,683	($117)
Drug B	$1,800	0.38	$1,116	$1,515	$399
Drug C	$1,300	0.24	$988	$1,094	$106
Drug D	$530	0.03	$514	$446	($68)
Drug E	$460	0.06	$432	$387	($45)
Drug F	$220	0.12	$194	$185	($8)
Drug G	$110	0.18	$90	$93	$2
Avg Rebate		0.16			

More alarmingly, artificial price transparency creates economic incentives for manufacturers to mitigate subsidization within a competing category or class by negotiating rebates that approximate the average for a category or class. A rational manufacturer would be compelled to compute their best estimation of the average rebate in the category or class which would have the effect of standardizing rebates toward the mean.

Artificial price transparency additionally creates perverse incentives for manufacturers with new-to-market products to engage in a strategy to negotiate the lowest possible rebate agreements with plans to enjoy the benefit of higher rebated drugs already within the category or class. Offering any rebate – preferably the lowest or one that approaches the estimated mean – inserts the manufacturer's drug into the POS rebate calculation by category or class. This delivers the advantage of being cross-subsidized by the weighted average rebate, which includes rebated drugs already competing in the class, to artificially lower the negotiated price of the new market entrant. This confers an anti-competitive advantage over existing competitors in the category or class, with entry into the market at a negotiated price point inured solely from its competition.

Pharmacy Price Concessions Included in Negotiated Price at POS

The proposed rule would revise the definition of "negotiated price" to remove the "reasonably determined" exception and require all price concessions from pharmacies be reflected in the negotiated price that is made available at the POS and reported to CMS on a PDE record, even when such concessions are contingent upon performance by the pharmacy.

Comment: Humana recommends that CMS continue to permit post-POS performance-based pharmacy price concessions and allow such amounts to be reported as DIR (as opposed to being reflected in the negotiated price).

Humana's approach with performance-based contracting with network pharmacies closely aligns with our value-based payment initiatives for providers, hospitals, and other health care providers. In all of our value-based reimbursement programs, we seek to improve the quality of care delivered to our members by more closely aligning reimbursement with patient outcomes and moving away from a traditional fee-for-service reimbursement model. Humana's Quality Network (QN) is also modeled, in part, on CMS's Star Ratings Program, which awards performance incentives based on a plan's performance relative to its competitors based on performance measures developed by the Pharmacy Quality Alliance (PQA) and other organizations. During the development of the program, Humana received recommendations from Pharmacy Quality Solutions (PQS), the 3rd party vendor jointly owned by PQA, in the design of the QN to ensure high performing pharmacies were rewarded under the same methodology used in the CMS Stars Program for plans.

The concept of paying for value and quality can be seen in numerous value-based payment models in the private and public sectors, including those implemented or proposed by CMS. For example, the shared savings concept of the CMS Accountable Care Organizations (ACOs) or the up-front discount applied in the Comprehensive Care for Joint Replacement (CJR) Model are emerging value-based models developed by CMS. In fact, CMS data on plan Star Ratings indicates that over the previous four years, less than 20% of Medicare plans have been awarded bonus payments for the highest performance level (4.5 or 5 Star overall) and less than 50% of plans have been awarded bonus payments for the 4 Star or above performance.[49] Further, in CMS's hospital Star Ratings Program, only 2.2% of hospitals are awarded the highest performance (5 Star overall).[50] Humana is applying these same concepts to pharmacy care delivery under the same methodology that is applied to plans and hospitals to improve quality of care for seniors in the Medicare program. Performance-based arrangements do not lend themselves to being reflected at the POS. These arrangements should not be

[49] 2016 Star Ratings Fact Sheet accessed at https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/performancedata.html

[50] Data Brief: Evaluation of National Distributions of Overall Hospital Quality Star Ratings accessed at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-21-2.html

discouraged or prohibited, because they provide significant benefits and savings to the Part D program and proposing such changes raises legal concerns.

The Proposal Would Increase Premiums and Program Costs. The proposal of eliminating DIR from pharmacies as a method to reduce beneficiary costs would result in higher premiums for all enrollees and would increase costs for the government and taxpayers. According to CMS's own analysis of POS pharmacy price concession impacts, in Table 11 (82 Fed. Reg. at 56428), enrollees are expected to experience a $5.7 billion increase in premium costs and the government a $16.6 billion increase in total costs over 10 years. Humana's own analysis similarly confirms this proposal would increase enrollee premiums and total government costs. Post-POS (DIR) price concessions cause a greater reduction in federal Medicare spending than equivalent drug discounts reflected at POS. Such amounts are reflected in lower plan premiums and are allocated to reduce Federal Direct subsidy payments.

Additionally, performance-based pharmacy price concessions paid to plan sponsors through DIR do not increase Part D program costs as long as they are used to reduce member premiums. Furthermore, DIR allows sponsors to pass pharmacy savings through to all plan members, ensuring that **all** beneficiaries benefit from the savings. Many PDP beneficiaries have a preference for experiencing savings through lower premiums and reduced cost sharing rather than through lower negotiated prices at the pharmacy counter.

The RFI Would Eviscerate Preferred Pharmacy Networks. CMS has long supported a PDP sponsor's statutory ability to reduce cost-sharing or coinsurance for certain preferred pharmacies meeting a PDP sponsor's special terms and conditions. Indeed, in the preamble to the proposed rule, CMS reiterates its goal of "ensur[ing] that plan sponsors can continue to develop and maintain preferred networks while fully complying with the any willing pharmacy requirement." 82 Fed. Reg. 56,336, 56,371 (November 28, 2017). Yet, by interfering in the negotiations between PDP sponsors and pharmacies, and by requiring all price concessions be included in the negotiated price, CMS would significantly hinder the ability of PDP sponsors to craft preferred networks. Simply put – CMS has long interpreted AWP as "allowing Part D plans to reduce cost-sharing differentially for network pharmacies" (70 Fed. Reg. 4,194, 4,254 (January 28, 2005) – but now proposes to place severe limits on this flexibility by requiring all price concessions be passed through at POS, regardless of a pharmacy's ability to meet a PDP sponsor's special terms and conditions.

The Proposed Rule Threatens the Existence of Performance-Based Quality Programs, that Currently Provide Positive Value. Humana strongly believes that Part D sponsors should retain the flexibility to use performance-based pharmacy price concessions to lower negotiated prices and/or to report them as DIR. However, the proposed rule, by treating all post-POS performance-based pharmacy price concessions in the same manner, fails to distinguish between those price concessions which lend themselves to

being reflected at the POS. Some post-POS price concessions, such as pharmacy negotiated penalty and/or fee-based performance targets, are not capable of being determined and included in the negotiated price since they are impossible to determine prospectively. Price concessions of this nature are based on future performance such as generic dispensing rates, medication adherence, or other performance measures. These types of post-POS price concessions which reduce costs to the government and reduce premiums for beneficiaries, have broader Part D program benefits and should not be discouraged. For example, pharmacy DIR can help increase generic dispensing rates (GDR); where every one percentage point increase in the GDR would save the Part D program and beneficiaries an estimated $68.9 billion over the next ten years.[51] As well, performance-based DIR helps increase medication adherence which is crucial to improving patients' health outcomes. Humana's QN, which uses performance-based incentives in the form of pharmacy DIR, has contributed to strengthening patient medication adherence. Of the Humana Medicare Part D members who were non-adherent (Proportion of Days Covered (PDC) < 80%) in 2016, 61.8% of them are now adherent (PDC > 80%) in 2017 with implementation of the QN.

Moreover, it is important to allow sponsors to have penalties in their toolbox to manage costs, in addition to incentives. Even though the proposed rule would permit Part D sponsors to make additional incentive payments to pharmacies after the POS, potential financial penalties can be more effective at influencing behavior than potential financial bonuses. Individuals are generally more sensitive and averse to the risk of financial losses compared to the potential for additional gains. This reality is reflected in the willingness of providers to participate in shared savings-only payment structures, while being reluctant to assume downside risk.

The Proposal Would Result in Decreased Reimbursement Rates for All Pharmacies and Therefore Reduce Pharmacy Network Size. As a result of this proposed rule, the reimbursement rates offered to all pharmacies in the future could be significantly decreased. This decline in reimbursement rates, along with performance-based quality programs no longer being incentivized, could result in contracting terms that may not be financially favorable to pharmacies. Many pharmacies may decide to no longer participate in the network, and therefore, the current network of 60,000 pharmacies will likely contract, thus reducing consumer access to broad pharmacy networks.

The Proposal is Inconsistent with the Statute. The proposed definition of "negotiated prices" violates the plain language of 42 U.S.C. § 1395w-102(d)(1)(B). The statute requires that negotiated prices "shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations." Had Congress intended that all negotiated price concessions be passed through to beneficiaries, they would have used a phrase other than "take into account" in the definition of the term "negotiated prices." Indeed, CMS admits in the RFI the lack

[51] https://www.pcmanet.org/wp-content/uploads/2017/07/Value-of-PDP-DIR_20170706.pdf

of legal authority it has in changing what is a very clear statutory provision. CMS notes "Under current law, when not explicitly required to do so for certain types of pharmacy price concessions, Part D sponsors can choose whether to reflect various price concessions, including manufacturer rebates, they or their intermediaries receive in the negotiated price." CMS also concedes in the preamble that the plain language of the statute "contemplates that Part D sponsors have some flexibility in determining how to apply manufacturer rebates [and pharmacy price concessions] in order to reduce costs under the plan.

Under the Part D statute, CMS is prohibited from "interfere[ing] with the negotiations between drug manufacturers and pharmacies and PDP sponsors." 42 U.S.C. § 1395w-111(i)(1). This provision has long been understood as prohibiting CMS from interfering in payment negotiations between both PDP sponsors and pharmacies, and PDP sponsors and manufacturers.

In the RFI, CMS contemplates a limit on the degree to which PDP sponsors negotiate pharmacy price concessions outside of those applied at POS. By requiring that all price concessions be included in the negotiated price, PDP sponsors and their PBMs will lose the ability to negotiate upside and downside incentives with pharmacies tied to performance or quality targets. Thus, to the extent the RFI would mandate that these concessions be included in the negotiated price, as opposed to being reflected as DIR, it would clearly constitute interference in PDP sponsor negotiations. Such allocation of price concessions is appropriately the subject of business negotiations between Part D sponsors and pharmacies. Under the statute, CMS may not interfere in those negotiations.

Proposal in the RFI is Incompatible with the Coverage Gap Program. In the RFI, CMS notes a major legal hurdle in adoption of its proposal: for purposes of calculation of manufacturer liability under the coverage gap, the statute references the term "negotiated price" as it was defined in regulations at the time of the passage of the Affordable Care Act. Notably, this regulatory definition in place in 2010 references only the price concessions that the Part D sponsor had elected to pass-through at POS. As such, if CMS were to adopt the policies in the proposed rule, it would be de facto adopting two different definitions of "negotiated price" for purpose of the Part D program. CMS is, therefore, rightly concerned that it may not have the legal authority to require PDP sponsors to include pharmacy price concessions in the negotiated price for purposes of determining the coverage gap amount

RFI Timing and Effective Date are Problematic. This rule will not be finalized in time to be part of the Advance Notice and Draft Call Letter for CY2019. Moreover, plans are already in contract negotiations based upon current regulations.

Concluding comments: As MedPAC notes, the CMS RFI proposals "would be complex to implement, administratively burdensome and, for drug classes with few competing

therapies, would risk disclosure of confidential rebate information."[52] Burdensome DIR regulations will not fundamentally reduce costs across the program. Instead, Humana believes that competition is the key to reducing drug prices for Medicare beneficiaries. Recently, in an interview with Avik Roy for Forbes, CMS Administrator Verma stated the following:

> *"If we go in and look at out-of-pocket expenses, even in out-of-pocket expenses we show that it's a very small percentage of people that are seeing an escalation in prices where their out-of-pocket expenses are over $7,000 or over $10,000. Then even narrowing in there, I think where the issue is in drug pricing is where there are no competitors. The market works very well when there are competitors and that's where drug prices are more controlled or more managed. The issue becomes when you have new drugs that come out on the market, high value, that's where I think it's problematic when there are no competitors. There's also plenty of examples of what I call bad actors or issues. I think we all remember the stories around EpiPen, but it's really around those new drugs that are coming out, those high cost drugs. Those present challenges not only in the Part B program, Part D, but also for our Medicaid programs where state budgets are not prepared when a new drug, and I think we saw this with the hepatitis C drugs that came out, new drugs coming out on the market, very expensive, and they're not prepared to pay for it because of the way their budgets work. I think that, that's where we have the challenge."*[53]

Humana thanks the Administrator for her thoughtful and balanced commentary. We agree that there are challenges in Medicare Part D, but they are, in context, issues generally limited to breakdowns in competition. Hepatitis C is a good example of the challenge of an emerging market. When Sovaldi launched in April 2014, plans received little in rebates. If CMS had a POS rebate policy at that time it would have had little impact. According to CMS data, in 2014 over $3.1 billion was spent in Part D on Sovaldi.[54] Now with multiple competitors in the class, prices are stabilizing and more rebates are available. **As President Trump has tweeted, competition is essential to reducing prices.[55]Accordingly, Humana strongly urges CMS to work with other Federal Agencies to remove barriers to prescription competition and regulations that are abused in anticompetitive ways.** We specifically recommend the Administration address the following abuses of regulations or anticompetitive behaviors:

- **Work with the Health Resources and Services Administration (HRSA) to ensure that 340b rebates are passed through to Part D beneficiaries –** currently 340b

[52] January 3, 2018 MedPAC letter to Administrator Seema Verma
[53] Avik Roy, CMS Chief Seema Verma Speaks About Her Top Health Care Policy Priorities, Forbes, 12/17/2017, video available online at https://www.forbes.com/sites/theapothecary/2017/12/05/cms-chief-seema-verma-speaks-about-her-top-health-care-policy-priorities/
[54] CMS Part D Prescriber National Summary Report, Calendar Year 2014
[55] See https://twitter.com/realDonaldTrump/status/839110000870109184

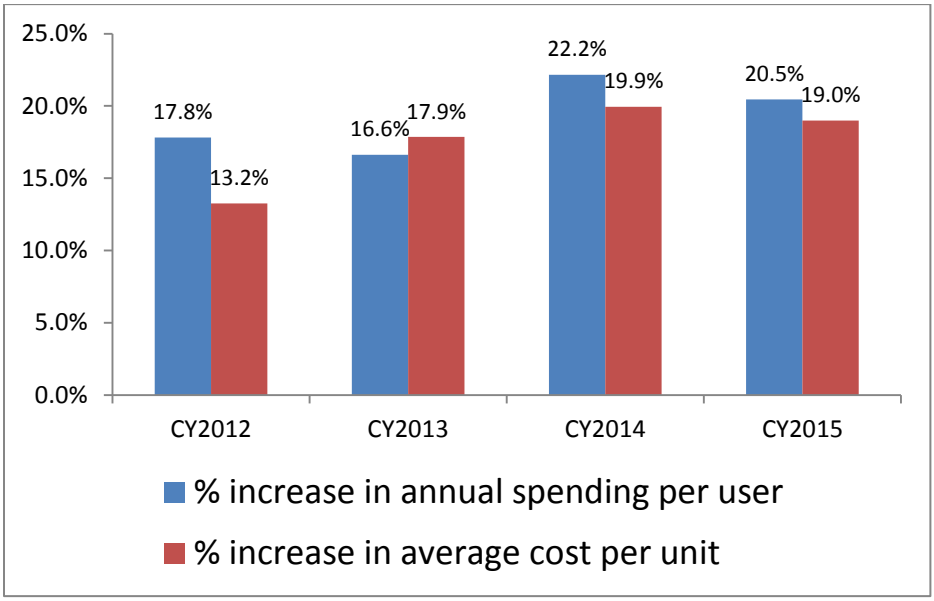
entities are not required to pass through or even share price reductions with Part D beneficiaries, plans, or the Medicare Trust Fund. CMS and the Administration should work, with Congress if necessary, to remedy this situation.

- **Limit abuses of the Part D protected classes –** as Humana has noted in previous comment letters, the requirement that plans cover all or substantially all products in the six protected therapeutic categories reduces competition between drugs in those classes and contributes to increased costs. Indeed, Humana generally receives roughly 1/7th of the average DIR for protected class brand drugs compared to other brand drugs and the inflation rate of list prices for protected class brand drugs has been higher the last two years than the inflation rate for other brands. The protected classes have also been abused. For example, the reduced utilization management of protected classes created an environment where there was overuse of antipsychotics. As the HHS Inspector General noted, "these powerful, at times dangerous drugs were often prescribed for uses that are not approved by the Food and Drug Administration and do not qualify as medically accepted for Medicare coverage. Potentially most alarming, 88 percent of the time these drugs were prescribed for elderly patients with dementia, a population the FDA has warned faces an increased risk of death from this class of drugs."[56] Another example is Lyrica (pregabalin), an anticonvulsant protected class drug manufactured by Pfizer. Lyrica qualifies for protected class status because it is FDA-approved for the treatment of partial on-set seizures (when in used in combination with other drugs), but the product is more commonly used to treat various neuropathic pain conditions and fibromyalgia which have no protected class status. For further evidence, one need look no further than Pfizer's national marketing strategy which predominantly focuses on promoting the drug for fibromyalgia, diabetic nerve pain, and spinal cord injury nerve pain – **not** epileptic seizures.[57] As illustrated in the figure below, CMS public use data demonstrate that Lyrica has had very high percentage increases in both annual spending per user and average cost per unit of the drug. We believe these increases would be unlikely if Lyrica did not have protected class status. Accordingly, CMS should consider eliminating protected class protections for drugs that are subsequently approved for non-protected class indications or apply protected class rules only in cases where a drug is prescribed for the treatment of an indication to which a protected class protection applies.

[56] See https://oig.hhs.gov/newsroom/testimony-and-speeches/levinson_051011.asp

[57] Pfizer website for Lyrica lists seizures last http://www.lyrica.com/ and their tv ads have focused on diabetic nerve pain, see for example https://www.youtube.com/watch?v=UbQ6PbDdzuw

Trends in the annual growth of spending per user and the average cost per unit of Lyrica in Medicare Part D[58]



- **Leverage CMS data to illustrate the cost impacts of anticompetitive behaviors like patent evergreening -** extension of a brand drug's patent exclusivity through the development of new formulations or products that offer clinically insignificant additional benefits has been referred to as evergreening or product hopping. This is clearly anticompetitive as it blocks legitimate market entry of generics. Take for example, Forest Laboratories' Namenda (memantine HCl) tablets versus the extended release (XR) formulation. Namenda is indicated for the treatment of moderate to severe Alzheimer's disease. The 5/10mg tablets were going off patent in April 2015. Forest created a "new" version called Namenda XR (the extended release version of the drug) and obtained a new patent, allowing it an additional 14 years without generic competition.[59]In 2015, the first year with generic memantine HCl tablets, the annual per user cost decreased -23.8% down to CY2011 levels in Part D. By contrast the patent protected Namenda XL increased in annual per user cost by 52.2% in CY2015 from CY2014.[60] CMS is best positioned to leverage its claims from Parts A, B, and D to empirically illustrate the Medicare Trust Fund and beneficiary impacts associated with these and other anticompetitive behaviors.

[58] CMS public use data available online at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Downloads/2015_Medicare_Drug_Spending_Data.zip

[59] Michael Carrier and Steve Shadowen, "Pharmaceutical Product Hopping: A Proposed Framerwork for Antitrust Analysis," Health Affairs Blog, June 1, 2017; Patrick G. Boen, M.D. Senior Director, Clinical Development at Forest Research Institute, February 2014 letter to providers announcing plans "to discontinue the sale of NAMENDA (memantine HCl) tablets on August 15, 2014.

[60] Analysis of CMS "Medicare_Drug_Spending_PartD_All_Drugs_YTD_2015_12_06_2016" file

II.B.2. Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503 and 423.504)

CMS proposes deleting the references to first tier, downstream, and related entities (FDRs) in the compliance program training requirements at §§422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C). As such, CMS proposes to delete the provisions of the Part C and Part D regulations that require use of the CMS-developed compliance training for FDRs. Compliance training would still be required of MA and Part D sponsors, their employees, chief executives or senior administrators, managers, and governing body members and CMS will continue to hold MA organizations and Part D sponsors accountable for the failures of their FDRs to comply with Medicare program requirements, even with these proposed changes.

> **Comments:** Humana appreciates the ongoing collaboration with CMS to make improvements to the compliance training requirements. We have received many comments from FDRs over the past several years regarding the burden of the compliance training. **As a result, we are supportive of the proposed FDR training changes, particularly the deletion of the requirement to use the CMS-developed compliance training with FDRs, as this will provide greater flexibility in how we administer our compliance program and reduce the burden of this training for sponsoring organizations and their FDRs.** However, plan sponsors often cite CMS requirements as the basis for requiring completion of compliance training programs with our FDRs. In the absence of regulatory language requiring FDRs to comply with plan sponsor compliance program assurance processes, we anticipate FDRs will continue to challenge how plan sponsors choose to oversee their FDRs related to compliance program requirements. **Humana requests that CMS provide language in the final rule specifying that FDRs must comply with plan sponsor compliance program assurance processes.**

II.B.4. Revisions to Timing and Method of Disclosure Requirements (§§422.111 and 423.128)

CMS proposes two changes to the disclosure requirements. First, CMS proposes to revise §§ 422.111(a)(3) and 423.128(a)(3) to require MA plans and Part D Sponsors to provide the Evidence of Coverage (EOC) by the first day of the annual enrollment period, rather than 15 days before. In addition, CMS proposes to modify § 422.111(h)(2)(ii) to permit MA and Part D sponsors to provide the EOC, Summary of Benefits, formulary, and provider network information on the plan's website or electronically, with hard copies to be made available "upon request."

> **Comments**: **Humana supports the proposal to change the required delivery date of the EOC, Summary of Benefits, formulary, and provider network information to the first day of the annual enrollment period. We also support the proposal to allow plans to provide these documents in electronic format or via hard copy, whichever is the enrollee's preferred format, as this will alleviate consumer confusion and dissatisfaction related to the volume of mail they receive from their MA plan.**

We respectfully request that CMS also include the LIS Rider as part of this proposed change in document flexibility. Per Chapter 13 of the Medicare Prescription Drug Benefit Manual, "Part D Sponsors must send the LIS Rider at least once a year to their members at the same time as the combined EOC and [Plan Annual Notice of Change] ANOC."[61] Additionally, LIS enrollees are instructed, via medicare.gov, to keep the LIS rider they receive from their plan sponsor with their EOC so that it can be referred to if an enrollee has questions about their costs.[62] Given that the proposal allows beneficiaries the choice to receive their EOC electronically, and that LIS enrollees receive the LIS rider at the same time as the EOC and are instructed by Medicare to keep the rider with their EOC document, it follows that it would be appropriate for plans to provide the LIS rider electronically to an enrollee who has chosen to receive their EOC documents electronically. This will reduce beneficiary confusion, as it could be perplexing for an enrollee opting for electronic documents to subsequently receive a mailed paper copy of a document meant to be paired with a document they received electronically. It would also result in reduced administrative burden for plan sponsors. Humana agrees that, similar to the approach with Provider/Pharmacy Directories and Formulary, a notice should be sent to LIS enrollees to provide them with the option of either accessing the EOC and LIS Rider electronically or requesting a hard copy version of the document.

In order to facilitate disclosure to enrollees of the option to receive documents electronically, we recommend an alternative to sending a separate, distinct notice to enrollees. Humana encourages CMS to update the model ANOC 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 that all information is contained in one document for easy enrollee accessibility, eliminating opportunities for the separate document to be misplaced. Amending the ANOC model in this way would also reduce the number of mailings, especially large volume documents, that plans are required to send to enrollees, an issue that consumer testing has proven to be overwhelming to enrollees, as CMS itself notes in the proposed rule.

II.B.5. Revisions to §§ 422 and 423 Subpart V, Communication /Marketing Materials and Activities

CMS proposes several changes to Subpart V of §§ 422 and 423 regulations in order to curtail and clarify which types of materials and activities are subject to agency review. CMS also proposes to establish standards for "communication materials" that fall outside of the new proposed definition of "marketing materials." In addition, the agency proposes to implement a mandated prohibition on marketing to individuals eligible for the new continuous open

[61] Medicare Prescription Drug Benefit Manual Chapter 13, Section 70.2; https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/Chapter13.pdf

[62] https://www.medicare.gov/forms-help-and-resources/mail-about-medicare/plan-lis-rider.html

enrollment and disenrollment period for MA and certain Part D members as required by the 21st Century Cures Act (Public Law 114-255).[63]

Comments: Humana supports the agency's proposal to narrow the scope of materials subject to agency review. We agree that the existing definition of "marketing materials under § 422.260(1)-(4) is overly broad. Consistent with the proposed rule, we encourage CMS to focus its oversight on plan marketing materials that have the highest potential of influencing a beneficiary's enrollment decision.

Specific items currently considered "marketing materials" that we recommend be re-categorized as "communication materials" include, but are not limited to:

- member outreach (letters, call scripts, postcards, emails, etc.) not intended to promote or sell a specific plan;
- press releases (even if benefits and network details are included, because these documents are not developed to influence enrollment decisions);
- multi-language inserts; and
- Explanation of Benefits and other documents pertaining to utilization of the plan.

In addition, the current filing requirements require all materials to be filed, whether for approval or as file and use. This creates a significant volume of materials to be submitted to CMS, even if those materials do not influence the enrollment decision or pose a risk of confusing or misleading beneficiaries about their current benefits or premiums. In 2016, Humana filed a total of 2,544 documents. Of those documents, 1,213 were alternate formats, non-marketing, and envelopes. Humana's recommendation is that CMS no longer require these materials to be filed. Plans would still be required to comply with all CMS marketing guidelines, but removal of the filing requirements will allow CMS to focus on those materials that have the greatest likelihood for a negative beneficiary experience.

Humana specifically recommends that CMS consider removing the filing requirements for the following materials:

- member letters – provider termination letters, non-payment of premium, etc.;
- press releases;
- foreign language materials;
- ID cards;
- online enrollment forms;
- envelopes;
- banner like ads; and
- multi-language inserts.

[63] https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf

When implementing the proposed changes via sub-regulatory guidance, we urge CMS to release guidance with the draft Call Letter in order to give MAOs sufficient time to prepare for the CY 2019 open enrollment period.

II.B.6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (§§ 423.590 and 423.636)

CMS is proposing to change the adjudication timeframe for Part D standard redetermination requests from 7 calendar days from the date the plan sponsor receives the request to 14 calendar days from the date the plan sponsor receives the request.

Comments: Humana supports the proposed change from 7 days to 14 days. We strongly concur with CMS that the proposal will significantly reduce autoforwards related to these specific case types. As CMS moves toward implementation of the proposal, we recommend that the agency issue new protocols to adjust the timeliness calculations for applicable Data Universe fields.

II.B.7. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE (§ 422.590)

In order to eliminate unnecessary paperwork and administrative expense, CMS is proposing to remove the requirement that MA plans notify an enrollee when a case has been forwarded to the IRE after an adverse decision.

Comments: Humana strongly supports CMS's efforts to eliminate duplicative processes and reduce administrative expenses. Consistent with the agency's new Patients Over Paperwork initiative, we encourage CMS to finalize its proposal to remove the requirement for plans to send an adverse determination notice indicating that a case has been referred to the IRE. As discussed in the proposed rule, beneficiaries already receive a similar notice from the IRE when their cases are referred. We believe that beneficiaries may be unnecessarily confused when receiving letters from both their plan and the IRE. As CMS moves toward implementation of the proposal, we recommend that the agency issue new protocols to adjust the timeliness calculations for applicable Data Universe fields.

II.B.8. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (§ 423.160)

CMS proposes to adopt the National Council for Prescription Drug Programs (NCPDP SCRIPT) version 2017071, on January 1, 2019, as the official Part D e-prescribing standard for the e-prescribing functions outlined in the proposed § 423.160(b)(1)(v) and (b)(2)(v), and for medication history as outlined in the proposed § 423.160(b)(4). Additionally CMS proposes retirement of NCPDP SCRIPT version 10.6 on December 31, 2018.

Comments: Humana appreciates the ongoing effort to adopt the most current version of the NCPDP SCRIPT standard in Part D in order for the industry to effectively and efficiently transmit appropriate data to and from physicians, pharmacies, and payers. Implementation of the NCPDP SCRIPT version 2017071 by January 1, 2019 and the

sunset of NCPDP SCRIPT 10.6 as proposed will not pose any major technical issues that would potentially delay implementation.

Additionally, Humana supports the use of electronic prior authorization as it reduces administrative burden on providers and speeds up access to therapy for patients. NCPDP SCRIPT version 2017071 supports electronic prior authorization transactions and **Humana seeks clarification from CMS as to whether electronic prior authorization is included in the list of required Part D transactions.** If electronic prior authorization is not included, we encourage CMS to add it as a Part D required transaction, as it can improve beneficiary and plan experience.

II.B.9. Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations (§§ 422.502(b)(1) and 423.503(b)(1))

CMS proposes to revise § 422.502(b)(1) and § 423.503(b)(1) to reduce the review period from 14 to 12 months. This would effectively establish a new review period for every application review cycle of March 1 of the year preceding the application submission deadline through February 28 (February 29 in leap years) of the year in which the application is submitted, and would eliminate the counting of instances of non-compliance in January and February of each year in two separate application cycles.

Comments: Humana supports the agency's proposal to reduce the application past performance review period from 14 to 12 months. We agree that a 12-month assessment more accurately reflects organization performance and appropriately resolves "double-counting" concerns. However, rather than a March – February look-back period spanning across calendar years, we recommend a January – December look-back period. A calendar year review period would provide the following advantages:

- **Objectively measures performance over a single plan year:** A January – December review period corresponds with the plan year and sequentially covers all CMS requirements, thereby providing a more complete assessment of overall performance. It also allows a MAO to more clearly determine where plan changes may have resulted in performance issues.

- **Allows CMS to issue results prior to the application deadline:** Concluding each performance review period at the end of the year would allow CMS the time to calculate and provide results to organizations prior to the application due date. Subsequently, plans with performance issues would be saved the time and effort of submitting an application, and CMS would be saved the time and effort required for the initial application review.

In addition to the agency's proposal, we encourage CMS to continue evaluating the process for potential modifications commensurate with the advancement of the MA and Prescription Drug Benefit programs. For example, compliance letter thresholds have decreased by an average of 76% between 2010 and 2017, indicating performance

improvement across all MAOs.[64] However, lower thresholds ultimately increase the impact of each letter and the likelihood that an entity will receive negative points. The impact is magnified for entities with more than one contract number, because the entire entity is prohibited from expanding, and the MAO from obtaining any new contracts, if a single contract meets the overall past performance thresholds.

Expansion prohibitions due to past performance can occur regardless of a plan's membership or overall Star Rating. Humana subsidiary, CarePlus Health Plans (H1019), was prohibited from expanding in CY 2017, despite its 4.5 Star Rating (CY 2016). Additionally, while CarePlus represented just 2% of Humana's overall membership, all Humana legal entities were prohibited from obtaining any new contract numbers in 2017. Likewise, all Humana legal entities were prohibited from obtaining new contract numbers in CY 2016 due to the past performance of three Humana Insurance Company contracts, representing only 8% of Humana's overall members.

We recommend that CMS revisit its current practice of denying new contracts to any entity owned by parent organizations of past performance outliers. While we strongly agree with the underlying intent of the existing policy, to discourage the expansion of poor performing plans, prohibiting new contracts in this manner disproportionately impacts parent organizations of multiple-contract entities. Such organizations may be denied new contracts based solely on the results of a single, small contract irrespective of overall legal entity or parent company performance, which ultimately stifles growth and competition in the MA market.

As an alternative, we recommend that CMS consider assessing past performance action at the contract, rather than the legal entity level. This approach prevents poor performing contracts from expanding, while not penalizing the legal entity from service area expansion opportunities.

In addition, we urge CMS to consider allowing multi-contract organizations with an outlier contracted subsidiary to obtain new contracts if all of the following conditions are met:

- **the parent legal entity has no more than one outlier contract for the most recent past performance review period;**
- **the negative performance points assigned to the outlier contract are not attributable to terminations; and**
- **the outlier contract comprises no more than 10% of the parent legal entity's total MA membership.**

II.B.10. Part D Prescriber Preclusion List (§ 423.120(c)(6))

CMS proposes to rescind the current provisions in § 423.120(c)(6) requiring physicians and eligible professionals to enroll in or to validly opt-out of Medicare in order for a Part D drug

[64] CMS 2013 Application Cycle Past Performance Review Methodology Update (December 2, 2011), p. 7; CMS 2019 Application Cycle Past Performance Review Methodology Update (November 28, 2011), p. 8.

prescribed by the physician or eligible professional to be covered. As a replacement, CMS proposes that a PDP sponsor must reject, or must require its pharmacy benefit manager to reject a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the "preclusion list," which would be defined in § 423.100 and would consist of certain prescribers who are currently revoked from the Medicare program under § 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation, is detrimental to the best interests of the Medicare program. However, CMS also proposes that in order to ensure continuity in therapy for beneficiaries, plan sponsors may not reject claims or deny beneficiary requests for reimbursement for a drug on the basis of the prescriber's inclusion on the preclusion list unless the sponsor has first covered a 90-day provisional supply of the drug and provide individualized written notice to the beneficiary that the drug is being covered on a provisional basis.

Comment: Humana appreciates CMS's willingness to rescind the rule that required prescribers to enroll or opt-out of Medicare in order for a beneficiary to have their prescription covered by their plan. **However, we are strongly opposed to the provisional coverage requirement proposal.** We also have the following additional concerns about the preclusion list proposal.

1. **Humana requests clarification on what the key differences are between the proposed preclusion list and the Medicare Exclusion Database (MED).** The MED, derived from the Office of the Inspector General (OIG) List of Excluded Individuals/Entities containing all currently excluded providers, provides Part D sponsors with monthly provider sanctions and reinstatement files, through which plan sponsors can update their internal systems in order to effectively carry out current requirements related to claims processing. One of the proposed reasons for a provider to be included on the preclusion list is that the provider or entity is currently revoked from the Medicare program under § 424.535. § 424.535 discusses various reasons for revocation of Medicare billing privileges including (but not limited to) felonies, noncompliance, fraud, and abuse, reasons that closely resemble the OIG exclusions listed under 42 U.S.C. 1320a–7. As such, it follows that a provider may be included on both the MED and the proposed preclusion list. This scenario, under which a provider or entity is on both lists, could present an operational challenge for plan sponsors, as provisional fills do not apply to drugs prescribed by providers on the MED, but under this proposed rule, CMS would require plan sponsors to provide 90-day provisional fills for members prescribed a Part D drug by a prescriber on the preclusion list. Humana recommends that CMS consider not including providers on the MED on the CMS preclusion list to eliminate any duplication and to ensure plan sponsors have more clarity surrounding whether a provisional fill is required, should the provisional fill proposal be finalized.

2. The proposed effective date for the preclusion list provisions is now January 1, 2019. While Humana appreciates the extended implementation window, new information technology will need to be in place in order for us to effectively implement these provisions. Additionally, end-to-end testing must occur in order to avoid any member disruption. As such, **we urge CMS to delay implementation of the preclusion list provisions until January 1, 2020.**

   Humana will need clear and concise requirements from CMS on how updates to the preclusion list will work and many other outstanding issues which were not addressed in the proposed rule. More guidance will be needed on how physicians are added to or removed from the preclusion during the month, and how situations should be handled when a physician is on both the preclusion and MED lists. While we understand that some of these questions will be answered in the file layout, past experience with the testing and development of previous iterations of regulatory guidance on Part D prescriber exclusion requirements and numerous industry conversations with Center for Program Integrity officials during which this issue has been communicated, demonstrate that payers will need at least one year from the time the file layout is released for proper implementation. **Due to the shortened implementation timeline and without any file layout or requirements having been released, we strongly urge CMS to defer the implementation date to January 1, 2020 and to ensure that plan sponsors have the file layout at least one year in advance of this date.**

3. **Humana strongly opposes the proposal to maintain the provisional coverage requirement, and we urge CMS not to finalize this proposal.** If a prescriber is on the preclusion list, it does not seem appropriate for Humana or for the Medicare Part D program to provide a 90-day supply of medication to the beneficiary under that specific excluded physician's request. Currently, there are no provisional fills required if a provider is on the MED file, therefore Humana questions why CMS would now require provisional fills for providers on the preclusion list. If the requirement for the provisional fill is maintained, Humana will need at least 12 months for its implementation. Within those twelve months, plan sponsors would need the provisional fill requirements released by CMS, including model beneficiary notice letters, guidance to better understand how provisional fills work when a prescriber is on both the preclusion and MED lists, as well as how provisional fills function in relation to the existing transitional fill requirements.

II.B.10.c. Part C, MA Cost Plan, and PACE Preclusion List (§ 422.224)

For CY 2019, CMS is removing the MA provider enrollment requirement. As a replacement, CMS proposes that a MAO shall not make payment for an item or service furnished by an individual or entity that is on a CMS created ''preclusion list.'' The preclusion list, which would be defined in § 422.2, would consist of certain individuals and entities who are currently revoked from the Medicare program under § 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the individual or entity to

the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation is detrimental to the best interests of the Medicare program.

Comments: Humana supports CMS's proposal to remove the MA provider enrollment requirement. We have been concerned that the enrollment requirement would result in a high volume of claims payment denials due to non-enrollment of providers, leading to a negative beneficiary and provider experience over which a MA plan sponsor would have little control. Humana appreciates the opportunity to collaborate with CMS regarding the implementation of the Part C preclusion list and we support the following approaches with regard to implementation of the Part C preclusion list:

1. **Modifier for Urgently Needed and Emergency Services** – CMS proposes to change Section § 422.224 to state that a "MA organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 422.113 of this chapter) furnished to a Medicare enrollee by any individual or entity that is excluded by the OIG or is included on the preclusion list." In its proposed rule, CMS does not specifically mention how the agency plans on implementing the exception for emergency and urgently needed services furnished by a provider on the preclusion list. **Therefore, Humana suggests that CMS create a Healthcare Common Procedure Coding System (HCPCS) modifier for this exception to allow for timely, automated processing of claims.**

   If a provider on the preclusion list furnishes a service that meets the definition under Section § 422.113 for emergency or urgently needed services, then that provider should be required to include the assigned modifier on a claim. This modifier would alleviate the need for payers to manually review every claim in case a rare urgently needed or emergency service exception might apply. CMS currently has this exact same processing mechanism in place for providers who have opted-out of Medicare. Those providers must submit claims using HCPCS modifier GJ to signal that an urgently needed or emergency exception applies. CMS should create a separate and distinct modifier for preclusion list providers. Humana does recognize that there are a potentially limited number of HCPCS modifiers available. If the modifier scarcity concern warrants sufficient merit to outweigh the creation of a new modifier then, alternatively, Humana suggests CMS edit the GJ modifier so that it is required to be used by providers on the preclusion list in addition to Medicare opt-out providers.

2. **Timing of Notice and Appeal Rights** – The proposed rule would add Section § 422.222(a) to the Code of Federal Regulations, allowing providers on the preclusion list to appeal their inclusion. Any appeal under this proposed provision, however, would be limited strictly to the provider's inclusion on the preclusion list; it would neither include nor affect appeals of payment denials or enrollment revocations, because there are separate appeals processes for these actions. CMS proposes to send written notice to the individual or entity of their inclusion on the preclusion list.

The notice would contain the reason for the inclusion and would inform the individual or entity of their appeal rights. While the proposed rule is clear on affording the provider the right to appeal determination of being listed on the preclusion list, the timing of the notice and appeal remains unclear.

The administrative burden on both providers and payers could be reduced by allowing providers to appeal before being included on the official preclusion list. Once the initial determination is made, CMS should immediately send notice of the initial determination and the reasoning for inclusion. This notice should include a grace period of a length that CMS deems sufficient to file an appeal. During this grace period, CMS should not place the provider on the preclusion list. If the provider does not file an appeal by the end of the grace period, CMS should then add the provider on the preclusion list. If provider does file an appeal, the provider should not be included on the preclusion list until the provider's appeal is upheld or the provider can no longer exercise the appeal options, whether due to lack of timely filing or because the appeals opportunity has been exhausted. By forgoing immediate inclusion on the preclusion list when the initial determination has been made, it will reduce potential provider burden by limiting the number of appeals a provider has to file. For example, if the provider was accidentally included on the preclusion list, the provider would have sufficient time to correct the issue without suffering from loss of revenue due to preclusion list-related denials. MA plans would also benefit from not having to manually overturn denials due to the provider's mistaken inclusion on the preclusion list. Such a manual process only extends for a longer time the period between services rendered and reimbursement for those services.

3. **Clarification on the scenario if provider is on both OIG sanction list and CMS preclusion list** – One of the proposed elements required for a provider to be eligible for inclusion on preclusion list is the "individual or entity is currently revoked from Medicare under § 424.535". (See CFR Section 422.2) As we mention previously in our comments on the Part D preclusion list proposal, CMS's reasons for revocation closely resemble the OIG exclusions listed under 42 U.S.C. 1320a–7 and thus, it follows that a provider could be on both lists. This presents difficulties from a plan sponsor operational standpoint, as provider remittances and member explanations of benefits can only report a single denial reason. **Humana recommends that CMS consider not including OIG excluded providers on the CMS preclusion list so providers and members have a singular reason for claims payment denial.** This would prevent duplication in the event the provider is on both lists for the exact same reason. It will also provide a clear route for a provider to take in order to seek a remedy in the event of a mistake, if they know specifically which list they are included on that led to the claims payment denial. In the event CMS does not decide to exclude OIG sanctioned providers from the preclusion list, **Humana suggests that CMS clarify which reason for denial would take precedent over the other.**

4. **Delay preclusion list implementation** – The proposed effective date for the preclusion list provisions is now January 1, 2019. New information technology will need to be in place in order for MAOs to effectively implement these provisions and end-to-end testing must occur in order to avoid any member disruption. As mentioned previously in our comments on the proposed Part D preclusion list, plan sponsors will need additional guidance from CMS in order to implement the preclusion list, including information on how providers are added or removed from the list during the month, how plan sponsors should treat providers included on both the OIG exclusion list and the proposed preclusion list, and the new file layout. As such, **we urge CMS to delay implementation of the preclusion list provisions until January 1, 2020 and to ensure the file layout is released at least one year in advance of this date.**

II.B.13. Reducing Provider Burden – Comment Solicitation

CMS expressed interest in stakeholder feedback on provider burden related to producing medical record documentation for MAOs. For the purposes of these comments we draw not only on our extensive experience as an MAO, but also as a Management Services Organization (MSO) providing population health services supporting practices in understanding, managing, and administering health care coverage for their populations through integrated population analytics and value-based models of care.[65] Humana has also conducted relevant survey work with provider organizations including the AAFP.[66]

Comments: At a high level, MAOs are required and incentivized by CMS policy to request medical records from providers for the following six reasons:

1. Clinical Coverage Decisions – (Part C and Part D) pre- and post-service benefit administration;
2. CMS audits/other governmental audits;
3. CMS Risk Adjustment;
4. HEDIS and Stars measurement;
5. Plan Compliance/fraud, waste and abuse (FWA) audits and investigations and FWA prevention, such as prior authorization requirements related to potential opioid abuse; and
6. Grievance and appeals adjudication.

We believe there are several regulatory actions CMS can take to reduce the need for multiple requests for medical records. First and foremost, CMS must prioritize the alignment of HEDIS and MA/Part D Stars with other CMS quality systems. As we have commented before, we believe that the U.S. healthcare system places a tremendous

[65] MSO services are provided to over 1,500 clinicians by Humana's subsidiary Transcend. For more details see https://www.transcendinsights.com/about_transcend_insights/

[66] See for example, "Study Details Growing Acceptance of Value-based Payments Among Family Physicians, but Barriers Still Exist" available online at http://press.humana.com/press-release/study-details-growing-acceptance-value-based-payments-among-family-physicians-barriers

measurement burden on providers that likely adds unnecessary administrative costs and diverts attention away from clinical practice. Indeed, a recent study published in *Health Affairs* found that physician practices in four common specialties spend 785 hours per physician and $15.4 billion in aggregate dealing with the reporting of quality measures.[67] Moreover, recent surveys conducted by the Medical Group Management Association (MGMA) and KPMG with the American Medical Association (AMA), have found that the majority of providers find CMS quality systems, like the Merit-Based Incentive Payment System (MIPS) to be burdensome.[68]

To alleviate the reporting burden on providers, Humana strongly urges CMS to more closely align MA and Part D Stars measures with other quality systems. While some Stars measures are specific to the administration of plans (e.g., member complaints), the majority of Stars measures are determined based on provider performance. An analysis conducted by the actuarial firm Milliman found that approximately 65% of the Stars quality measures relating to physician performance have a similar corollary measure in the MIPS.[69] Ideally, the percentage of overlap would be much higher, and it is important to note that this overlap often is limited to the measurement concept or domain level. In other words, even when both traditional Medicare and MA measure the same concept (e.g., All-Cause Readmissions) there can be important technical distinctions in how data are pulled, from whom, and how risk or case mix adjustments are performed between the two systems. Functionally, this means that providers must support multiple measurement processes, thus increasing their burden. **We therefore encourage CMS to seek ways to limit the differences between MA/Part D Stars and other CMS quality systems like MIPS. CMS should also seek to reduce the total number of quality metrics**. For plans, there are currently, 34 Part C Stars measures, 14 Part D Stars measures, and 43 HEDIS measures to report.[70] For providers, the CMS Quality Measures Inventory contains a staggering 2,189 potential measures.[71] CMS, both the Center for Medicare Stars' team and the Center for Clinical Standards and Quality, should work with providers and plans to achieve these burden reduction goals.

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[67] Casalino, Lawrence P., et al. "US physician practices spend more than $15.4 billion annually to report quality measures." Health Affairs 35.3 (2016): 401-406.

[68] MGMA 2017 Regulatory Burden Survey Report http://www.mgma.com/getattachment/Government-Affairs/Advocacy/Advocacy-(1)/MGMA-2017-Regulatory-Relief-Survey/MGMA-Regulatory-Relief-Survey-Results.pdf and KPMG, "Physicians Found to be Unprepared for Quality Reporting: Survey," available online at https://home.kpmg.com/us/en/home/media/press-releases/2017/06/physicians-found-to-be-unprepared-for-quality-reporting-survey.html

[69] http://www.milliman.com/insight/2017/MACRA-and-Medicare-Advantage-plans-Synergies-and-potential-opportunities/

[70] CMS, Medicare 2018 Part C & D Star Ratings Technical Notes, 09/28/2017 and CMS HEDIS® 2016 Documentation available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/MA-HEDIS-Public-Use-Files.html?DLSort=1&DLEntries=10&DLPage=1&DLSortDir=descending

[71] CMS Quality Measures Inventory available online at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/CMSMeasuresInventory20171103.xlsx

CMS also noted in the proposed rule that there is an assessment of the "beneficiaries' experiences with their health and drug plans through the CAHPS survey. Physicians also interact with health and drug plans on a daily basis on behalf of their patients. We are considering developing a survey tool for collecting standardized information on physicians' experiences with health and drug plans." For the provider burden reasons expressed above, we do not support creating a Physician CAHPS survey.

Second, CMS should share FFS claims data with stand-alone PDPs. PDP members are generally enrolled in FFS Medicare for medical services. Currently, CMS does not provide FFS claims to PDPs on their own members. This requires PDPs to seek out data from providers that would be unnecessary if CMS merely shared its FFS claims data with plans on a timely basis. We note that Section 704(g)(2)(B) of CARA requires the Secretary to convene stakeholder meetings to discuss a variety of topics, including the sharing of FFS Medicare claims data with PDP sponsors.

Third, CMS should be flexible with the dates of service (DOS) requirement for medical records supporting risk adjustment data. Under current rules and auditing practices, CMS requires medical records with a DOS within the risk adjustment data collection period.[72] This effectively means the plan must request medical record information on the patient every year that the individual is an enrollee, even if there is no change in the enrollee's clinical status. **This policy is burdensome on providers and plans and makes little sense when it involves diseases/conditions that have no current cure, such as, human immunodeficiency virus (HIV) and amputations.**

Fourth, CMS and HHS should support health data standards that promote interoperability of medical records and systems. If our collective health information technology were interoperable, burden on providers for information requests would be significantly decreased. Humana recommends supporting the Fast Healthcare Interoperability Resources (FHIR) specification.[73] Developed by industry stakeholders in Health Level Seven International (HL7), FHIR "aims to simplify implementation without sacrificing information integrity. It leverages existing logical and theoretical models to provide a consistent, easy to implement, and rigorous mechanism for exchanging data between healthcare applications." FHIR is used by CMS contractors like RelayHealth and the Medicare Part D Transaction Facilitator and Humana leverages FHIR in the Transcend Insights' population health management platform, HealthLogix.[74]

II.C.1. Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements (§§ 422.2420 and 423.2430)

[72] CMS, Contract-Level RADV Medical Record Reviewer Guidance,09/27/2017 and CMS Medicare Managed Care Manual Chapter 7 – Risk Adjustment

[73] See https://www.hl7.org/fhir/overview.html

[74] For more background on the Humana/Transcend perspective see https://www.transcendinsights.com/interoperability-healthcare-closing-gap-patient-expectations-reality/

For contract year 2014 and subsequent contract years, MAOs and Part D sponsors are required to report their medical loss ratios (MLRs). The MLR reflects how much of a plan's total revenue is spent on claims for medical services, medications, and certain other qualifying expenses like quality improvement activities. Plans are subject to financial and other penalties for a failure to meet the statutory requirement that they have an MLR of at least 85 percent. CMS is proposing to significantly reduce the amount of MLR data that MAOs and Part D sponsors submit to CMS on an annual basis. Under the proposed rule, MAOs and Part D sponsors would only report the MLR percentage and amount of any remittance owed to CMS for each contract. CMS is also proposing to revise the MLR calculation to include in the MLR numerator expenditures related to fraud reduction activities (including fraud prevention, fraud detection, and fraud recovery) and Medication Therapy Management programs.[75]

> **Comments:** Humana appreciates the ability to provide feedback on proposed enhancements to existing MLR regulations. **Humana agrees and fully supports the proposed change to the treatment of expenditures on fraud reduction activities. The proposed changes would better acknowledge the efforts MAOs and Part D sponsors make to combat fraud, waste, and abuse and the benefits realized therefrom. In terms of the types of activities that should be allowed we suggest an alignment to CMS's definitions of fraud and abuse.** As an example; *"Expenditures on activities that are designed to identify claims payments resultant from intentional deception or misrepresentation (or) provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicare program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care."* This definition would support CMS's efforts to increase potential savings for the government, taxpayers, and beneficiaries as well as leading to higher levels of health care quality. Accordingly, classification as a quality improvement activity seems appropriate. **The inclusion as a quality improvement activity may require additional clarification or scoping of exclusions in § 422.2430(b). Specifically, § 422.2430(b)(1) excludes expenditures that are designed to control or contain costs, which is seemingly broad and might create confusion. If this definition was amended to exclude expenditures on fraud reduction activities, it would more directly support inclusion of these costs.**

II.C.5. Physician Incentive Plans (PIP) – Update Stop Loss Protection Requirements (§ 422.208)

CMS proposes to modify § 422.208 to update current stop-loss deductible limits and to codify the methodology for updating stop-loss deductible limits in future years.

> **Comments: We support the proposed stop-loss deductible limits and the methodology for updating stop-loss deductible limits in future years.**

[75] Available online at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-11-16.html

CMS proposes to authorize MAOs to use actuarially equivalent arrangements to protect substantial financial loss under the PIP.

Comments: We are concerned that this proposal will add complexity, confusion, and administrative burden for MAOs – likely nullifying any benefit of added flexibility.

CMS proposes to allow non-risk patient equivalents (such as Medicare FFS patients) to be included when determining the stop-loss deductible.

Comments: While we support CMS's proposal, we request that CMS issue guidance regarding how the proposed inclusion of net premiums earned (NPE) at § 422.208(f)(2)(vii) will interact with the current pooling requirements set forth in § 422.208(g). We recommend that CMS delete the existing pooling requirements and replace them with § 422.208(f)(2)(vii) or clarify that determining a provider's panel size can be done at the MSO or independent physician association (IPA) level (rather than the physician group level or individual physician level) and reconsider whether all five pooling criteria should be required.

CMS seeks comment on whether the definition of "substantial financial risk" and "risk threshold" contained in current regulation should be revisited, including whether current identification of 25% of potential payments remains appropriate in light of changes in medical costs.

Comments: Humana recommends that CMS modify the definition of "substantial financial risk" to remove bonus-only arrangements. Alternatively, CMS could consider applying a distinct definition of "risk threshold" to bonus-only arrangements such that the threshold for substantial financial risk is raised above the current standard of bonuses that exceed 33% of total potential payments, minus the bonus.

In addition, we recommend that CMS consider the following approaches, which are designed to better harmonize PIP stop-loss requirements with recent advancements in value-based contracting between MAOs and providers.

1. **Exclude bonus or withhold compensation if a certain portion is tied, in part, to non-referral cost factors.** The current "substantial financial risk" definition does not apply to bonuses or withholds that are not based on use of referrals, such as quality of care furnished, patient satisfaction, or committee participation. But the rules are not clear about how they would apply to bonus or withholds that take into account both referral service costs and quality of care, for example.

2. **Amend the definition of "substantial financial risk" to exclude bonus arrangements where the physician or physician group must meet minimum quality performance thresholds in order to be eligible to receive the bonus.** If the policy reason for the PIP rules is to avoid creating large financial incentives for avoiding medically

necessary care, then applying well-designed minimum quality performance thresholds would ensure that beneficiaries are not negatively impacted. Such a change would reflect that many bonus/withhold arrangements are not solely based on quality measurement or management of referral costs, but are instead a combination of the two.

3. **Clarify that the "substantial financial risk" test applies only to bonuses or withholds to individual physicians, not the group practice.** In the case of incentive arrangements between an MAO and a physician group, or a downstream arrangement between an IPA and a physician group, CMS's PIP rules should permit the physician group entity to contract for larger bonuses and withholds without requiring stop-loss, as long as the group provides an attestation that individual physician compensation does not meet the substantial financial risk definition.

   This proposal would allow the physician group entity to retain larger bonus incentives to cover administrative and quality improvement costs that are essential investments for physician groups to successfully manage their attributed population. This would also put physician groups on par with ACOs, physician-hospital organizations (PHOs), or IPAs that contract with networks of physicians, where these intermediaries are currently permitted to contract for substantial financial risk without stop-loss coverage as long as their downstream agreements do not trigger substantial financial risk. In such arrangements, the ACO, PHO, or IPA entities typically will retain the excess bonus amounts to cover their own overhead costs and allow them to make the necessary investments for population health management. The current PIP rules advantage these intermediary entities relative to physician groups, and encourage form over substance in how MAO arrangements with physician groups and intermediaries are structured.

   For example, if a physician group establishes a wholly-owned MSO lay entity to hold the bonus/withhold contract with the MAO, then the MSO entity could retain any excess bonus amounts as long as the downstream physician group payment arrangement does not trigger substantial financial risk. Under this arrangement, physicians owning the MSO could still access the additional bonus amounts through their ownership stakes in the MSO rather than through their participation agreements. This is an example of how the current PIP rules privilege form over substance. The PIP rules would be much more workable if they applied only to the payments received by individual physicians for management of referral costs.

II.C.7. Changes to the Agent/Broker Requirements (§§ 422.2272(e) and 423.2272(e))

CMS proposes to eliminate §§ 422.2272(e) and 423.2272(e), which currently require MAOs to terminate any employed agent/broker who becomes unlicensed. MAOs will instead be allowed to determine the appropriate level of discipline when an agent becomes unlicensed. The prohibition on MAOs contracting or hiring an agent without the appropriate state license will remain in place.

Comments: Humana concurs with the proposal and appreciates CMS's recognition of the difficulties faced by MAOs in implementing the rule as originally written. This change will provide a more level playing field for MAOs and will provide agents the opportunity to correct a lapse in license instead of mandatory termination.