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January 16, 2018

The Honorable Seema Verma,
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201
Submitted electronically via regulations.gov

Dear Administrator Verma:

AARP is pleased to submit the following comments on the Proposed Rule for the CY 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, Medicare Prescription Drug Benefits and PACE programs. AARP, with its nearly 38 million members in all 50 States and the District of Columbia, Puerto Rico, and U.S. Virgin Islands, is a nonpartisan, nonprofit, nationwide organization that helps people turn their goals and dreams into real possibilities, strengthens communities and fights for the issues that matter most to families such as healthcare, employment and income security, retirement planning, affordable utilities and protection from financial abuse.

Comprehensive Addiction and Recovery Act of 2016 (CARA) Definition of “exempted beneficiary” (Sec. 423.100)

The proposed rule codifies the provisions of CARA, which provides authority for Medicare Advantage Prescription Drug (MA-PD) plans and Prescription Drug Plans to establish a drug management program limiting access to frequently abused drugs for people determined to be at risk of abusing those drugs. It also provides a process for plans to follow in limiting such access.

Under CARA, certain beneficiaries are exempt from those drug management programs. CARA specifically exempts enrollees who are receiving hospice care and residents in a long-term care facility for which frequently abused drugs are dispensed through a contract with a single pharmacy. CARA also gives CMS the authority to exempt other

individuals. CMS proposes to use that additional authority to also exempt individuals with a cancer diagnosis.

CMS requested feedback on whether other groups should be exempted from CARA's drug management process. AARP appreciates and continues to support CMS' efforts to reduce opioid abuse, but we are concerned that efforts to detect and prevent overutilization may inadvertently result in beneficiaries being unable to obtain necessary and appropriate medications. For example, many analyses of pain prevalence find that, in addition to beneficiaries struggling with the pain associated with cancer at the end of their lives, many patients with other conditions, such as congestive heart failure, chronic obstructive pulmonary disease, stroke, and ALS also experience significant pain at the end of their lives.¹ As such, we recommend that CMS regularly re-evaluate which groups are exempted from CARA's drug management process and add groups as needed based on clear and convincing evidence.

Finally, AARP continues to believe any program to address prescription drug fraud and abuse in Part D must focus not only on enrollees, but also on prescribers and pharmacies that often contribute to fraud and abuse problems.

Flexibility in the Medicare Advantage Uniformity Requirements

AARP is concerned about CMS' proposal, beginning for the 2019 plan year, to relax the requirement that Medicare Advantage plans offer all enrollees access to the same benefits at the same level of cost sharing. Under the proposed revised policy, a Medicare Advantage organization (MAO) could offer specific tailored supplemental benefits and offer lower deductibles for enrollees that meet specific medical criteria if all enrollees who meet the identified criteria are treated the same. In addition, as discussed below, CMS proposes revising its policy to exercise uniformity flexibility within each segment of an MA plan.

AARP has supported efforts to allow greater flexibility in the Medicare Advantage program in order to better meet consumers' needs and to encourage greater value. However, we want to ensure that the criteria for value and increased flexibility is grounded by a firm basis in objective evidence of improved beneficiary outcomes and does not encourage discriminatory treatment of higher-risk beneficiaries. As such, we do not believe that the changes CMS proposes in the regulation meets this standard and we are concerned about the potential that the changes could instead lead to harmful outcomes.

We believe that such a departure from the statutorily required uniformity requirements may not be appropriate without a change in law and would be premature given that CMS's Center for Medicare & Medicaid Innovation (CMMI) has a demonstration of value-based insurance design that is underway (with an expanded demonstration in the works) for which the results of an independent evaluation are not available. We

¹ <http://www.clinicaladvisor.com/hospital-medicine/palliative-care-pain-management/article/603983/> and Colvin L, Forbes K, Fallon M; Difficult pain. BMJ. 2006 May 6332(7549):1081-3.

appreciate CMS' acknowledgement of its obligation under its proposed change to continue to monitor potential discrimination if a plan is targeting cost-sharing reductions and additional supplemental benefits for a large number of disease conditions while excluding other higher-cost conditions. Nonetheless, we believe that the proposed new benefit and cost-sharing flexibilities will give rise to increased complexity of benefit design, reduce the transparency required to ensure clear and understandable benefit and cost-sharing features of each plan and increase the potential for risk segmentation based on plan benefit design. We are also very concerned about CMS' capacity to adequately provide oversight to prevent potential discrimination, which will become a significantly more challenging task under the proposed changes.

Segmented Benefits Flexibility

AARP's concerns described above about CMS' proposed changes related to plan flexibility in benefit and cost sharing extend to its proposed change to allow plan segments (county-level portions of a plan's service area) to vary by benefits in addition to varying by premium and cost sharing. CMS' proposed interpretation contrasts with the current policy prohibiting such segment variation. We view this proposed change as contributing to more rather than less program complexity and we worry about the capacity of CMS to carefully scrutinize the compliance of any one MA organization's plan variations when many more variations are likely to arise as a result of this proposed change. We strongly urge CMS to more carefully evaluate the potential impact this change could have on promoting regional disparities, which we believe could be a significant concern.

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

One of the attractions of Medicare Advantage for beneficiaries is the out-of-pocket limit on cost-sharing for Parts A and B services, a feature not offered by traditional Medicare. AARP believes that the current maximum out-of-pocket limits help ensure that higher-risk beneficiaries are not discouraged from enrolling in Medicare Advantage plans. The voluntary limits can also serve to encourage plan options with even lower out-of-pocket cost maximums as a way to differentiate in the market and compete for consumers. Out-of-pocket limits are an attractive benefit for some beneficiaries seeking to reduce their overall annual out-of-pocket exposure. We appreciate that fee-for-service data for determining these annual limits is not ideal and we support CMS' proposed transition to the use of Medicare Advantage encounter data once these data are complete, and found to be valid and reliable. However, we urge that any future changes to the maximum out-of-pocket limits not add to beneficiary financial exposure.

Cost-Sharing Limits for Medicare Parts A and B Services (§§ 417.454 and 422.100)

AARP strongly supports CMS' current policies designed to safeguard enrollees in Medicare Advantage plans from cost-sharing requirements that could have a discriminatory effect against individuals who have higher-cost medical conditions. For this reason, we oppose any step away from those safeguards, including its current cost-

sharing limits which are set for Medicare Parts A and B services that tend to be used by sicker enrollees. As in the case of the above proposal related to the CMS methodology for calculating total out-of-pocket costs, we appreciate why shifting from Medicare FFS to MA encounter data could eventually provide for a more accurate accounting of patient utilization scenarios and length of stays or services used by average or sicker patients. However, we urge CMS to wait until the encounter data are more complete and accurate before implementing that change.

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

AARP does not support CMS' proposal to eliminate the meaningful difference test for Medicare Advantage bid submissions and bid review. We appreciate that CMS plans to retain other provisions of current regulations that help to safeguard beneficiaries from discriminatory benefit design. However, we believe that if CMS drops the meaningful difference requirement, the number of plan options offered by any one MAO in an area will proliferate, without providing any significant improvement in the array of choices offered to beneficiaries. Instead, the increased number of options is likely to make it even more difficult for beneficiaries and those who help them navigate the Medicare Advantage program to choose among the different plan options. Given the complexity of sorting through differences in premiums, cost-sharing features, plan provider networks and more, even those beneficiaries who are the most insurance literate face challenges today in making plan selections. While various tools are available to assist beneficiaries, and improvements have been made to the Medicare Plan Finder, such tools are not alone sufficient to help consumers discern meaningful differences between plan choices, and thus the meaningful difference test is necessary. We are also concerned that eliminating the meaningful difference test may encourage plan risk segmentation based on benefit design.

Coordination of Enrollment and Disenrollment through MA Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68)

AARP strongly supports freedom of choice for all Medicare beneficiaries. Therefore, we do not support auto enrollment of Medicare beneficiaries into Medicare Special Needs Plans (SNPs). Should CMS still decide to pursue the default enrollment process, clear and timely information must be provided to beneficiaries about their right to opt out of the SNP along with clear opt out processes. This information must be provided in a culturally competent/language appropriate manner. In addition, AARP cannot support auto enrollment of beneficiaries into any Medicare Advantage organization that has not achieved the highest quality rating.

CMS also proposes to permit simplified elections for "seamless" continuation of coverage for other (non-Medicaid) newly-eligible beneficiaries who are in non-Medicare health coverage offered by the same parent organization that offers a Medicare Advantage plan. As part of this proposal, CMS would provide that this simplified election would be available for a beneficiary's entire Initial Coverage Election Period. CMS

characterizes this proposed change as one that would simplify the election process for individuals who could, if they want to, continue with the same parent organization's Medicare Advantage plan.

AARP believes that Medicare beneficiaries should have a genuine choice among Medicare coverage options and private health plans. We are concerned with efforts that effectively "steer" beneficiaries into private plan options without providing meaningful choice. We appreciate CMS' recent examination of such seamless enrollment arrangements and their proposal to require an "opt-in" rather than an "opt-out".

We remain concerned, however, that it may not be clear to consumers that the covered benefits of the MA plan may be very different from the organization's commercial product, including with respect to critical aspects such as the provider network and cost-sharing requirements. Such differences elevate the need for timely and understandable advance notice about the existence and implications of the arrangement so that affected beneficiaries know that they can decide to go elsewhere. If CMS finalizes this proposal, AARP urges that it ensure through guidance and enforcement that the Medicare Advantage organizations provide the required notice and do not in any way interfere with the individuals' right to choose traditional Medicare coverage and to access Medigap coverage on a guaranteed issue basis during the entirety of their Initial Coverage Election Period. Moreover, beneficiaries should only be able to elect such a simplified process into the highest quality rated plans, and not into lower rated plans.

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

CMS proposes to permit passive enrollment for full-benefit dually eligible beneficiaries from a non-renewing integrated D-SNP to another comparable plan if a number of conditions are met. These include that the passive enrollment is 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. In addition, the comparable plans would have to be highly integrated; have substantially similar provider and facility networks and Medicare- and Medicaid-covered benefits; could not prohibit new enrollment imposed by CMS; and have appropriate limits on premium and cost-sharing for beneficiaries. An eligible plan for passive enrollment also would have to achieve a minimum overall MA Star Rating for the year prior to the receipt of the passive enrollment beneficiaries of at least three stars. However, low-enrollment contracts or new plans without Star Ratings would be eligible for passive enrollment as long as the plan met all other proposed requirements. All affected beneficiaries would be provided with a SEP which lasts for two months.

AARP strongly believes that these important consumer protections should be included if CMS is to finalize this proposal. Moreover, we urge CMS to consider a higher minimum quality threshold than three stars, or require that plans achieve three stars for the prior

three years. Again, we believe that passive enrollment should be reserved only for the highest performing plans and we are not confident that three star plans or plans that have no immediately prior star ratings record should be approved for passive enrollment. Moreover, CMS should provide affected individuals with clear notice about the existence and implications of the arrangement, their alternative options for Medicare coverage, including comparable plans that have achieved at least three stars for the prior year, and ensure that consumers have effective ability to opt out.

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

AARP appreciates CMS's ongoing review of its Part D formulary policy and its recognition of the increased beneficiary challenges in navigating plan formularies with the rising numbers of plan formulary cost-sharing tiers and increasing complexity of those tiering structures. As CMS reports, almost all Part D plan benefit packages for the 2017 plan year offer drugs through tiered formularies and over 98 percent of those tiered benefit packages contain two generic-labeled tiers. Many of these contain a mix of generic and brand products. This alone can lead to significant beneficiary confusion as they seek out a plan that best meets their individual needs. We find it even more troubling that, in this plan year, almost two-thirds of all tiered plan benefit packages can exempt three of their five or six tiers from a tiering exception. The exceptions process was designed to allow enrollees under certain circumstances to pay the lower preferred cost sharing amount for non-preferred drugs.

AARP thus supports CMS' proposal which, in general, would base an enrollee's eligibility for a tiering exception "on the lowest applicable cost-sharing for the tier containing the preferred alternative drug(s) for treatment of the enrollee's health condition in relation to the cost sharing of the requested, higher-cost drug and not based on the formulary tiering label." AARP also supports CMS' more specific proposal to prohibit a Part D plan from excluding from its tiering exceptions process a tier that contains alternative drug(s) with more favorable cost-sharing solely because that lower-cost tier is dedicated to generic drugs. Similarly, we welcome CMS' proposal to codify that authorized generic drugs be treated as generics for purposes of tiering exceptions.

We anticipate that the changes discussed above, if finalized, will address some of the excess complexity of formulary tiering design as it affects the exceptions process. The extent to which they improve upon the current situation, however, depends on the exceptions process becoming less confusing and complicated to navigate. Earlier this year, the Medicare Payment Advisory Commission (MedPAC) reported that in its review of Part D's exceptions and appeals process, it found that the process can be time consuming, frustrating and burdensome for some individuals. Moreover, CMS' data show that a significant share of audited Part D plans have difficulties in this arena. For example, many give enrollees too little information about the rationale for a coverage denial or fail to demonstrate that they have reached out to prescribers for additional information to make a coverage decision.² In this light, we strongly urge CMS to make

² Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2017, http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf

the exceptions process as beneficiary-friendly as possible, including requiring a decision within fourteen days for determinations. In addition, AARP continues to encourage CMS to undertake broader efforts to educate beneficiaries and other stakeholders on the Part D exceptions and appeals process.

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

AARP has concerns about the potential adverse impact of CMS's proposed tightening of the Part D Special Election Period (SEP) for dual eligible beneficiaries. Under the current continuous SEP, a Part D eligible individual may enroll in or disenroll from a PDP and enroll in another Prescription Drug Plan or Medicare Advantage Prescription Drug (MA-PD) plan, as applicable, at any time if the individual is a full-benefit dual eligible or other low-income individual who is eligible for the Part D low-income subsidy (LIS).

Under the proposed rule, however, the SEPs for duals and other LIS eligible beneficiaries would be limited to circumstances within a certain period of time after a CMS enrollment or state-initiated enrollment or as a onetime annual opportunity that could be used at any time of the year. A separate SEP would be established that could be used by any dual or other LIS beneficiary within a certain period of time after a change to an individual's low-income subsidy eligible or Medicaid status. (These SEPs would not apply in the case of individuals identified as potentially at-risk or at-risk with respect to misuse or abuse of frequently abused drugs such as opioids).

In the event that CMS finalizes changes in the SEP policy for this population of Part D beneficiaries, AARP believes that those changes should be accompanied by robust consumer outreach and an education component so as to inform beneficiaries and those who help them of these changes and potential consequences to them in terms of access to their prescribed medications and the implications for their out-of-pocket costs. In addition, AARP strongly encourages CMS to monitor the impact of this change and be open to revisiting this policy if there is clear and convincing evidence that beneficiaries are being harmed.

Medicare Advantage and PDP Quality Rating System

CMS proposes to codify, with some proposed changes, the methodology for calculating Part C and Part D Star Ratings, and seeks comment on some specific issues. AARP strongly supports the use of the Star Ratings which provide helpful summary information to beneficiaries when choosing among MA and Part D plans. AARP supports the proposal that changes in measures used in the Star Ratings continue to be made through the annual Call Letter process, which provides opportunity for public comment.

Measures on Beneficiary Experience: CMS seeks stakeholder feedback on a number of topics, including whether it should consider adding measures that evaluate quality from the perspective of adding new technology or improving the ease, simplicity and satisfaction of the beneficiary experience in a plan. AARP strongly supports the development and use of such measures in the Star Ratings. In considering enrollment in an MA plan and in choosing among MA and Part D plans, beneficiaries are interested in learning about what plan interactions are like as well as assessments of health outcomes and patient experience with clinicians. In addition, Star Ratings should recognize plans that invest in new technology or other processes that make it easier for beneficiaries to make appointments and to interact with plan providers. CMS specifically mentions the use of telemedicine as an example of how plans might use new technology to assist beneficiaries. Measures that assess the use of telemedicine or other technologies should be designed to recognize plans that innovate in ways that improve health outcomes and beneficiary experience without inadvertently incentivizing plans to substitute telemedicine visits for in-person care when that is in the best interest of the beneficiary.

Plan-level Star Ratings: Comments are sought on whether CMS should consider calculating Star Ratings at the plan level instead of at the contract level, which is the current methodology that CMS proposes to continue and to codify. AARP strongly believes that beneficiaries should be given information on Star Ratings by plan because it is a plan they are choosing to enroll in, not a CMS contract. Having plan-level ratings would therefore permit beneficiaries to make more informed decisions about enrolling in a specific MA plan or a Part D plan. We recognize that not all plans will have sufficient data for CMS to calculate a meaningful plan-level Star Rating. We recommend that CMS calculate plan-level Star Ratings and substitute contract-level ratings only when a plan-level rating is not available due to data limitations. In that way, beneficiaries would continue to have some Star Rating information available to them if plan-level ratings are not available. The public display should make clear whether the Star Rating shown is for the plan or aggregated for multiple plans in a contract and this information should be provided in a way that is easy for the consumer to understand.

MedPAC has noted that contract-level quality reporting, particularly after contract consolidations, often combines performance for a wide geographic area, which makes contract-level Star Ratings less meaningful to beneficiaries seeking to understand plan differences in performance for their local geographic area. AARP recommends that CMS also consider moving to quality reporting at the local geographic area, which would provide the most useful information to beneficiaries choosing among MA and Part D plans.

Consolidations and Star Ratings: CMS proposes a change in how Star Ratings are assigned when contracts operated by the same parent organization and of the same plan type are consolidated. The current policy assigns the surviving contract's Star Ratings to the consolidated contract for the initial period after the consolidation. The Medicare Payment Advisory Commission (MedPAC) has noted that under the current methodology, consolidations have resulted in beneficiaries being moved from lower-

rated to higher-rated contracts, which has increased quality bonus payments to MAOs. It reports that about 20 percent of MA enrollment has been moved to bonus status over the past five years as a result of 108 consolidations. In particular, MedPAC found consolidation activity was particularly high in 2017, with 17 contracts moved to bonus status, affecting 1.7 million or 8 percent of enrollees.

AARP supports steps that would prevent consolidations from masking the performance of the consumed contracts. We therefore support the CMS proposal to assign Star Ratings using an enrollment-weighted mean of the measure scores of the contracts being consolidated. We would also support the alternative proposed by MedPAC under which contract Star Ratings would continue to be reported separately until the contract data being reported naturally reflect performance of the entire consolidated contract. We also urge that in addition to applying the proposed enrollment-weighted methodology or the MedPAC alternative to consolidations of contracts under the same parent organization, to the extent practicable, CMS should also extend the policy treatment to consolidations of contracts between different parent organizations. Finally, as noted above, AARP supports calculation of Star Ratings at the plan level where data permit. Should CMS adopt this approach in the future, the proposed enrollment-weighted methodology should be extended when consolidations occur under a plan-level Star Rating system. Also, as MedPAC has suggested, Star Ratings would be more useful for comparative purposes if they are calculated for a particular geographic area.

Measure Weights: CMS proposes to increase the weight given to patient experience/complaints measures when calculating the Summary Star Ratings for Part C and Part D plans and the Overall Star Ratings for MA-PD plan. AARP supports the increase in weight for these measures from the current weight of 1.5 to a weight between this level and 3, which is the weight currently given to outcome measures. Plans that perform well on patient experience and complaint measures should be rewarded in the summary and overall ratings; the weight given these measures should be closer to the outcome measure weight of 3 than to the weight of 1 given to process of care measures.

In addition, AARP supports the proposed codification of the special rule that began in 2017 for plans serving only Puerto Rico under which the medication adherence measures would be weighted at zero for the summary and overall rating calculations and maintained at a weight of 3 for the improvement measure calculations. We agree with CMS that this adjustment appropriately recognizes the unique challenges to medication adherence in Puerto Rico due to the lack of LIS there.

Categorical Adjustment Index: We continue to urge CMS to continue to work with stakeholders to review the reports and recommendations of the Assistant Secretary for Planning and Evaluation (ASPE), the National Quality Forum, measure stewards and others in order to replace the interim Categorical Adjustment Index (CAI) with an evidence-based, long-term policy regarding treatment of socioeconomic and disability status on Star Ratings. AARP stands ready to participate in this process. The potential for unintended consequences should be evaluated as part of this review. In particular,

AARP is concerned that the CAI or other adjustments may have the effect of masking differences in quality performance that are within the control of MAOs, and that could result in exacerbating quality disparities among plans serving vulnerable populations. All plans, including those with a high proportion of low-income and disabled enrollees, should have an ongoing incentive to improve quality performance. CMS should analyze data for potential differences in quality improvement among plans with and without a CAI. Further, CMS should undertake to identify and share best practices from experienced plans that are consistently high performing in serving LIS/dual eligibles.

Public Display of High- and Low- Performance Icons: AARP supports the proposed codification of the assignment of low-performance icons to contracts meeting criteria for poor performance over a three-year period. However, in assigning the high-performance icon, we encourage CMS to consider requiring a similar three-year period of high performance rather than the current policy one-year only. We strongly support the practice of giving beneficiaries special warnings of low-performance contracts which will encourage them to consider enrolling in other plan options where they are available.

AWP Standards Terms and Conditions and Better Definition of Pharmacy Types (§§ 423.100, 423.505)

AARP commends CMS' efforts to ensure convenient access to pharmacies and to keep pace with pharmacy innovation and new business models. We strongly believe that CMS must be vigilant in reviewing plans to ensure that pharmacy networks meet rigorous access standards, with appropriate monitoring and enforcement as essential elements. However, while AARP shares CMS' concerns about access to pharmacies, we question whether it would not be more expedient to develop and establish a fully transparent process that would evaluate plans' pharmacy network adequacy for their enrollees. Plan sponsors that consistently fail to meet CMS' pharmacy adequacy standards could then be required to open their networks more broadly. In the event that CMS finalizes these changes, AARP strongly recommends that CMS monitor the impact of this provision and remain willing to revisit the issue should these changes inadvertently lead to reduced competition and higher spending.

In addition, AARP supports CMS' efforts to ensure that Part D plan sponsors do not impede access to needed medications by requiring the use of specialty pharmacies for products that do not have specific safety or special handling requirements.

Changes to the Days' Supply Required by the Part D Transition Process (§423.120)

AARP opposes CMS' proposed reduction to the number of days of temporary supply that a new plan sponsor must provide for a drug that is not on the new plan's formulary (or for which prior authorization or step therapy is required). CMS proposes to shorten the required transition days' supply in the long-term care setting to the same transition supply currently required in the outpatient setting. This means that, if finalized, some

residents of nursing homes would only be able to receive a month's supply before the product can be denied.

AARP is concerned that providing for a shorter transition fill for residents of long-term care facilities would increase the likelihood that beneficiaries experience a lapse in their access to necessary pharmaceuticals. Residents of long-term care facilities generally have a much more limited access to prescribing physicians and those physicians tend to have a significantly limited visitation schedule. Under existing rules at §483.30(c), for residents in a nursing home for more than 3 months, a physician is only required to visit once every 60 to 70 days. Taking into account more limited access to physicians, a one month transitional supply of a necessary medical treatment may not provide an adequate amount of time for the often complex needs of residents who are often taking multiple drugs to successfully transition to a new drug regimen.

CMS indicates that it has not seen evidence that the transition period for people in a long-term care facility takes any longer than those receiving their prescription drugs from an outpatient provider. However, CMS does not provide any evidence or data to support this assertion. In our view, it is quite likely that the absence of problems for those in long-term care facilities is at least in part due to the longer transition period that has been available for those beneficiaries. Without better evidence that the transition policy is unnecessary, we strongly discourage CMS from finalizing this policy that could have a potentially harmful impact on many of Medicare's most vulnerable beneficiaries.

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

AARP supports CMS's proposed changes to permit Part D plans to make generic substitutions without obtaining advance CMS approval and for the plan to make additional changes in order to facilitate the use of certain generics by their Part D enrollees. We believe that the proposed changes would help to promote quicker shifts to generics and in so doing help to hold down the growth in drug costs for both beneficiaries and the Medicare program.

However, AARP is concerned by CMS' proposal to decrease the amount of direct notice required in cases where the removal of a brand drug or change in its cost-sharing status would affect enrollees taking the drug. CMS says its proposal would permit Part D sponsors to institute formulary changes in half the time and still afford enrollees sufficient time to either change to a covered alternative drug or to obtain needed prior authorization or an exception for the drug affected by the formulary change. However, we are concerned that 30 days may be too little time for some beneficiaries to connect with their prescribers about the implications of the formulary change and encourage CMS to retain their current policy.

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

AARP supports CMS' proposal to revise the definition of a generic drug to include follow-on biologics approved under section 351(k) of the PHS Act. As CMS clarifies, this revision would apply solely for purposes of Part D non-LIS catastrophic and LIS cost-sharing only. AARP strongly supports efforts to increase the availability and use of biosimilar products and believes that this change will help reduce out-of-pocket costs for Part D enrollees and the Medicare program.

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

AARP opposes CMS' proposal to eliminate the requirement on Part D plan sponsors to demonstrate the meaningful difference among their Prescription Drug Plan Enhanced Alternative offerings. We believe that this will make it more difficult for Medicare beneficiaries to distinguish and understand the different plan choices being offered in their area. Although the number of Part D plan offerings in an area is not as high as in Part D's early years, the reason for the small number is likely to be, in part, due to the meaningful difference requirement. Most beneficiaries still must navigate a wide array of choices, a task that is challenging for even the most educated beneficiaries. Moreover, by CMS' own estimates, as many as 125 additional enhanced plans (a 15 percent increase) could be offered as a result of this proposed change. Although we appreciate CMS' interest in encouraging greater competition and innovative plan designs, we believe that the proposed elimination of the meaningful difference standard for Enhanced Alternative plans is misguided.

Given our concerns about the need for clear distinctions among plan options, we are reassured that CMS has decided to maintain its requirement that Enhanced Alternative plan offerings be meaningfully different from the basic Part D plan offered by a plan sponsor in a service area. AARP would strongly oppose the elimination of the meaningful difference requirement in this regard.

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

CMS has requested comments on potentially applying manufacturer rebates and pharmacy price concessions to the price of a drug at the point of sale for prescription drugs covered by Part D plans. AARP shares CMS' goal of reducing out-of-pocket prescription drug costs for Medicare beneficiaries, especially for those who require high-cost drugs for chronic illnesses. In addition, we support efforts to increase transparency and accountability in the drug supply chain.

However, we are concerned that requiring manufacturer rebates and price concessions to be passed through at the point of sale could have unintended consequences and could lead to higher premiums for many beneficiaries. Currently, many Part D plans

sponsors opt to use part or all of the rebates they receive from manufacturers to keep the premiums associated with their Part D plans stable and reasonable³. AARP is concerned that requiring rebates to be passed through at the point-of-sale would remove this option and, as CMS already acknowledges, lead to higher premiums for most beneficiaries. In addition, it is unclear how many beneficiaries would see their out-of-pocket costs substantially decrease if rebates were required to be passed to the beneficiary at the point of sale, as many of the drugs included in protected classes rarely see sizable rebates.

AARP believes that any efforts to improve Medicare Part D should make such coverage more—not less—affordable for Part D enrollees. Consequently, we strongly urge CMS to conduct a comprehensive analysis to better understand the impact this change would have on out-of-pocket costs and Part D plan premiums before moving forward with any proposal to reconfigure existing rebate policies.

Moreover, AARP is concerned that requiring rebates and price concessions to be passed along at the point of sale could increase Medicare spending by disincentivizing manufacturers from providing higher rebates on brand-name drugs included in the Medicare Part D Coverage Gap Discount Program. In fact, CMS' analysis estimates that manufacturer rebates would be reduced over ten years by approximately \$10 billion to \$29 billion from point of sale rebates and by \$5 billion from point of sale pharmacy price concessions. Moreover, CMS also estimates that point of sale rebates and point of sale pharmacy price concessions would reduce funding for Medicare by approximately \$27 billion to \$82 billion and nearly \$17 billion, respectively, over ten years.

Finally, we note that this proposal does not address the root of Medicare Part D spending growth: high and growing prescription drug prices. While we share the goal of reducing costs for Medicare and its beneficiaries, we believe that reducing prescription drug prices will require using other existing authorities, including allowing for the safe importation of lower cost drugs, increasing transparency of drug prices, and eliminating barriers that reduce market competition. AARP stands ready to work with the Administration on commonsense solutions to combat rising prescription drug prices.

Communication/Marketing Materials and Activities (§§422 and 423)

Under existing rules, plan sponsors must submit marketing materials to CMS for review and approval. CMS' review ensures that the material does not misrepresent or inaccurately describe the plan or plan activities, and is not misleading. In some cases, CMS has created standardized language for certain marketing materials. Under the proposed rule, CMS would distinguish between “communications materials” and “marketing materials” and activities so that if finalized, certain plan communications which previously would have required CMS review and approval would no longer need to be reviewed and approved.

³ <https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf>

AARP is concerned that the proposed changes would undermine the improvements in plan communications that CMS has achieved to date. Oversight of marketing materials has helped ensure that plan information is accessible, understandable and accurate. Pulling back such oversight could reduce the clarity and accuracy of plan materials, hampering beneficiaries' ability to select the plan that best meets their needs.

If enacted, AARP strongly urges CMS to monitor the impact of this change and be willing to revisit or reverse course if there is clear evidence that beneficiaries are receiving inaccurate or incomplete plan materials.

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

AARP opposes CMS' proposal to eliminate requirements for Quality Improvement Projects (QIPs). CMS states that the QIPs are duplicative of other MAO activities including STAR Rating metrics. AARP believes it is premature to eliminate the QIPs without careful evaluation and consideration of where overlaps occur and which QIPs lead to the greatest improvements. Instead of eliminating the QIP projects for MAOs, we urge CMS when it issues mandatory topics for QIPs to take into account any relevant overlap to ensure QIPs are addressing the most important areas taking into account other related activities.

Thank you for the opportunity to share our comments on the proposed rule. If you have any additional questions, feel free to contact me or contact Amy Kelbick on our staff at akelbick@aarp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "David Certner". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

David Certner
Legislative Counsel and Legislative Policy Director