January 16, 2018

Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

Ms. Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–4182–P
P.O. Box 8013
Baltimore, MD 21244–8013

Re: Comments on Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Proposed Rule (CMS–4182–P)

Dear Administrator Verma:

Thank you for the opportunity to submit comments on 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 (Proposed Rule) published by the Centers for Medicare & Medicaid Services (CMS) on November 28, 2017. 82 Fed. Reg. 56336.

Aetna is one of the nation's leading diversified health benefit companies, providing members with resources to enable better informed decisions about their health. As one of the leaders in providing and managing benefits for Medicare and Medicaid beneficiaries, Aetna is committed to working with CMS and the Department of Health and Human Services (HHS) to formulate rules that advance consumers' top priorities: care quality, affordability, and choice. We appreciate the responsiveness of CMS to the feedback provided on the Request for Information (RFI) from May. Aetna believes we should be building health care around beneficiaries and measuring quality based on their expectations of a healthier, more active life than that of their parents. We commend this Administration for its efforts to put consumers first and improve the quality Medicare Advantage (MA).

Todays' consumers demand a modernized, innovative Medicare program. However, beneficiaries currently face an overwhelming amount of confusing information when choosing Medicare coverage that does not clearly articulate what they need to know. For example, 65 percent of seniors in traditional Medicare are unfamiliar with MA plans.[1] Further, studies have shown that as much as 60 percent of an individual's life expectancy is determined by social and environmental

[1] Better Medicare Alliance, *65% of Seniors on Medicare Are Unfamiliar with Medicare Advantage, available at:* http://bettermedicarealliance.org/newsroom/press-releases/65-seniors-medicare-are-unfamiliar-medicare-advantage (Oct. 30, 2017).

factors, as well as an individual's own behavior.[2] Given the potential of wellness and care management programs to help seniors live healthier lives, over 60 percent support the availability of these programs in MA.[3] If finalized, many of the proposals in this rule will address these, and other, consumer needs, increasing access to plans that address members' health and wellbeing.

The proposed flexibility, specifically around MA benefit offerings and the loosening of meaningful difference requirements for MA and Part D plans (collectively "MA plans"), will allow us to provide beneficiaries with higher quality care options that better meet their individual needs. We particularly applaud CMS' recognition that the Medicare uniform benefit requirement permits plans to design condition-specific programs that encourage beneficiaries to receive necessary care and assist beneficiaries in managing their conditions. We urge CMS to immediately release updated guidance clarifying that benefits such as meal delivery, transportation, communications devices, and wearables are critical to providing high quality health care and thus allowable supplemental benefits. Together with the proposals to streamline the information beneficiaries receive, these changes will improve Medicare's consumer experience.

In addition to these promising proposals, we encourage CMS to extend these flexibilities to Part D benefits given the critical importance of medication adherence to the management of chronic conditions. We also suggest CMS permit plans to include a care management component in condition-specific programs, to ensure that beneficiaries receive and take full advantage of enhanced benefits available to them. Engaged consumers are critical to ensuring smarter spending and healthier communities, but simplified enrollment options can reduce the frustration beneficiaries feel about engaging with Medicare. To this end, we are glad to see CMS reinstating seamless enrollment for Medicaid managed care enrollees and suggest CMS further explore this option, particularly for new Medicare beneficiaries. We believe that seamless enrollment policies will help ensure continuous high quality coverage, particularly for beneficiaries for whom the Medicare program is new.

Aetna believes that government can and should play a role in promoting transparency in prices for prescription drugs and encouraging lower-cost solutions for consumers. Aetna is aggressively pursuing new ways to manage drug costs and supports the testing of value-based payment arrangements for Part B drugs. Rising drug costs is the number one health care concern for consumers and we are committed to providing our enrollees with lower cost, effective treatments. That said, we are very concerned the changes CMS has outlined provide significant savings to manufacturers at the expense of taxpayers and higher premiums for all Part D enrollees. Based on our internal data, we believe this policy would reduce manufacturer liability by more than $1,000 annually compared with just over $400 in savings per beneficiary.

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[2] Steven A. Schroeder, M.D., *We Can Do Better – Improving the health of the American People,* New Eng. J. Med. 357:1221-8 (2007).

[3] Better Medicare Alliance, *65% of Seniors on Medicare Are Unfamiliar with Medicare Advantage, available at:* http://bettermedicarealliance.org/newsroom/press-releases/65-seniors-medicare-are-unfamiliar-medicare-advantage (Oct. 30, 2017).

We strongly urge CMS to consider alternative policy solutions that directly address the drug pricing issue and undertake additional notice and comment prior to requiring price concessions be passed through at the point-of-sale. We also note that health plans are subject to multiple regulatory reporting requirements limiting annual price increases and profits and provide the government with insight on our pricing strategies. Manufacturers face none of these oversight mechanisms and, as a result, consumers have little insight as to the true cost of their drugs.

We detail these recommendations, as well as additional comments on specific proposals, in the attached addendum. We would be happy to respond to any follow-up questions you may have.

Sincerely,

Steven B. Kelmar
Executive Vice President, Corporate Affairs
Aetna

Addendum
Detailed Comments on the Proposed Rule

We appreciate the opportunity to comment on this Proposed Rule. Our recommendations follow.

Benefit Flexibility

1. Flexibility in the Medicare Advantage Uniformity Requirements

We appreciate CMS' continued efforts to collaborate with MA plans to ensure they have the flexibility to design benefits in a way that ensures the most effective and efficient coverage for beneficiaries.

A. *Providing Access to Services Based on Condition or Disease*

We strongly agree that CMS has the authority to permit MA plans to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees who meet specific medical criteria, provided that similarly situated enrollees are treated the same ("tailored benefits"). Providing access to tailored benefits will help MA beneficiaries access benefits that are specific to their conditions, ultimately improving health outcomes and decreasing costs in Medicare overall. We are also supportive of CMS allowing these benefits to vary across segments.

We have already seen how tailoring benefits can help improve health outcomes for our beneficiaries through Aetna's value-based insurance design (VBID) demonstration program in Pennsylvania, where we offer our members with congestive heart failure (CHF) reduced cost sharing when they see primary care physicians and cardiologists. In addition, this VBID program goes further to increase adherence to health care services and medication by offering both a robust care management program and by reducing cost sharing for CHF beneficiaries for certain prescription drugs. These initiatives are aimed at preventing our beneficiaries with CHF from being re-admitted or having avoidable emergency visits. We therefore believe that CMS should extend these flexibilities to Part D prescription drug coverage.

- **Recommendations:**

  - **Finalize an interpretation of the uniform benefit requirements that enables MA plans to offer tailored supplemental benefits and reduced cost sharing to beneficiaries based on their clinical conditions.** We strongly support CMS' proposed interpretation and have long supported the flexibility to design plan benefit packages that are responsive to the health needs of our enrollees. As a participant in the VBID demonstration, we appreciate CMS' recognition that providing plans with greater flexibility has the potential to increase care quality and beneficiary satisfaction.

In addition, we would advocate that CMS consider ways to provide MA plans the flexibility to make benefits in lieu of benefits substitutions to best enable the plan to meet the needs of each unique member, including social determinants of health, perhaps via a demonstration or pilot.

- **Extend this flexibility to allow MA plans to reduce cost sharing for certain beneficiaries' Part D prescription drug benefits.** We urge CMS to extend tailored benefit design to Medicare Part D benefits as well. Beneficiaries with chronic conditions – the individuals this flexibility would help the most – are not only in need of health care services, but also must adhere to specific prescription drug treatment courses to manage their conditions. Medication is a critical part of most treatment plans, and the clinical benefit of effective medication adherence should not be ignored. Allowing this flexibility with respect to Part D benefits would help ensure they adhere to critical medication, ultimately reducing the chances of more serious health issues.

- **Finalize the ability to vary these targeted benefits across segments**.

- **Confirm that MA plans may choose to apply these flexibilities to out of network benefits**. We urge CMS to clarify that the ability to vary cost sharing applies to out of network services as well, should a plan choose, as long as it is offered to all beneficiaries with the same clinical conditions. As we have indicated, we support CMS' goal of allowing MA plans to offer benefit structures that encourage efficient, clinically appropriate treatment. This is perhaps even more important when a beneficiary chooses to seek out of network care, and it is particularly important for employer group MA plans that offer services under an extended service area waiver.

B. *Beneficiary Choice and Communications*

Our current VBID demonstration in Pennsylvania allows MA plans to require beneficiaries to opt in to the VBID program and participate in a care management program. This helps ensure benefits are appropriately targeted toward the beneficiaries that will most benefit. Based on our experiences in the VBID program, we have found that reduced cost sharing alone does not necessarily ensure beneficiary adherence to certain needed treatments. Participation in targeted care management programs as part of a tailored benefit design helps ensure that beneficiaries receive the appropriate services and understand and comply with the instructions and treatment plan specific to their conditions.

➢ **Recommendations:**

- **CMS should permit MA plans to require beneficiaries to actively participate in programs tailored to their specific health conditions.** Certain benefits are more effective if the recipient is actively participating in case management simultaneously.

Allowing MA plans to require active participation would help ensure Medicare payments are used appropriately and efficiently. For example, beneficiaries participating in a particular case management program receive reduced cost sharing for particular services or treatments. We do not believe this would run afoul of the nondiscrimination requirements as long as MA plans provide all beneficiaries with the same health condition the opportunity to participate with reasonable accommodations as appropriate, and the MA plan clearly communicates such care and management conditions or requirement when beneficiaries enroll (see next recommendation).

- **Additionally, we recommend that CMS consider transparent marketing flexibilities that enable MA plans to clearly and fairly communicate the benefits they offer.** To protect beneficiaries and to give enrollees options that meet their health care needs, CMS should give additional guidance on how MA plans can communicate these benefit variations and permissible marketing options, both for open enrollment and after plan enrollment to beneficiaries, both for clarity of choice and so beneficiaries can elect options tailored to their health care needs. For example, CMS could allow MA plans to describe the suite of programs they offer, so beneficiaries can sign up for coverage that best suits their needs. CMS could also allow MA plans to include information on these targeted benefits in the Annual Notice of Change (ANOC) and Summary of Benefits (SOB), which will help ensure beneficiaries understand these benefits could change if the person changed to another plan, even one run by the same parent organization.

C. *Allowed Supplemental Benefits*

We believe it is critical to allow MA plans to be able to provide supplemental benefits that go beyond medical benefits to provide beneficiaries the support they need to maintain consistent access to health services, adhere to medications, and generally optimize their health outcomes. As we have indicated previously, we believe the current statutory and regulatory definition of "supplemental benefits" would not preclude MA plans from offering a broader area of benefits designed to address social and environmental factors effecting beneficiaries' health, but believe the existing sub-regulatory definition of supplemental benefits is unnecessarily narrow. Currently, CMS requires that:

1. a supplemental benefit may not be a Medicare Part A or Part B covered service;
2. the item or service must be primarily health related; that is, the primary purpose of the item or service is to prevent, cure or diminish an illness or injury. If the primary purpose of the item or service is comfort, cosmetic or daily maintenance, then it is not eligible as a supplemental benefit. The primary purpose of an item or service is determined by national typical usages of most people using the item or service, or by community patterns of care; and
3. the MA plan must incur a non-zero direct medical cost in providing the benefit. If the MA plan only incurs an administrative cost, this requirement is not met.

Medicare Managed Care Manual, Chapter 4, Section 30.1, *available at:* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf (Apr. 22, 2016).

We strongly support CMS issuing updated guidance clarifying that MA plans may offer supplemental benefits, including social support services, for their most medically vulnerable beneficiaries, as they directly impact the health of a beneficiary and thus could meet the statutory requirement of being a "health benefit."

- **Recommendation: Immediately clarify via guidance with an opportunity to comment that MA plans may offer a broader array of supplemental benefits, including meals and nutrition services, transportation, housing assistance, communications devices, wearables, and other benefits that could help improve health outcomes for these beneficiaries.** We look forward to working with CMS to design coverage with benefits that help beneficiaries where they need it most.

2. Meaningful Difference

In addition to supporting flexibility around benefit offerings, we appreciate CMS' proposal to eliminate meaningful difference requirements for MA plan bids. We believe removing this requirement will help foster innovative plan choices, which will consequently give beneficiaries the opportunity to have access to plan designs that best fit their needs. We also understand and agree with CMS' continued interest in ensuring that MA plans are sufficiently different. While eliminating the meaningful difference requirement would not necessarily cause MA organizations to increase similar plan offerings, it would enable organizations to have flexibility to offer unique plan offerings. This increased flexibility would help CMS attain its goals of increasing choice and improving health outcomes for MA beneficiaries.

Moreover, it is crucial that beneficiaries fully understand the differences between MA plan offerings before selecting a particular plan. CMS can address concerns about beneficiary confusion among offerings by establishing certain guardrails. For example, CMS could require specific disclosures in marketing materials to ensure beneficiaries can effectively compare MA plans. Furthermore, we urge CMS to continue improving Medicare Plan Finder (MPF) and educating beneficiaries on the MA program. The need for a meaningful difference requirement is greatly mitigated by an MPF that allows beneficiaries to filter out the least applicable MA plans and search based on the criteria most important to them.

- **Recommendations:**

  - **Eliminate the meaningful difference requirement**. Eliminating this requirement will enable innovative plan designs in a way that best serves beneficiaries and give them optimal choices by ensuring MA plans are not making benefit changes simply to meet

regulatory requirements and that plan differences are aimed solely at meeting the needs of beneficiaries. Alternatively, if CMS decides to maintain this requirement we would recommend that CMS consider network and benefit structure differences in determining whether plan offerings are "meaningfully different."

- **Continue to devote resources to improving MPF, enabling beneficiaries to easily narrow down their choices based on personalized information.** We recommend CMS take steps to upgrade MPF in order to create a more consumer-oriented experience, similar to what consumers have come to expect when buying plane tickets or shopping on Amazon. For example, adding features that allow consumers to pre-select or "filter" criteria that are important to them would help narrow choices and thereby create less need to limit the number of plan options that are available for beneficiaries to choose from. Doing so would allow beneficiaries to make more informed choices when trying to decide if Original Medicare or MA is better for them, based on their needs, including greater ability to narrow down plan options if they choose to enroll in MA.

- **Consider establishing guardrails, including releasing specific marketing guidelines, to ensure that MA beneficiaries understand how an MA plan's offerings vary.** For example, MA plans can include information in their summaries of benefits or other pre-sale notices to communicate plan differences to members.

3. Maximum Out of Pocket (MOOP) and Cost-Sharing Limits

Similar to the other proposals that would provide greater benefit flexibility, we support CMS' proposal to update the data and methodology used to calculate the MOOP in the annual Call Letter and to consider changes to the voluntary MOOP limit, including creating additional levels and service categories. We believe these changes would afford us greater flexibility in our MA plan designs, while continuing to protect our members, and allow us to design benefit packages that are optimally aligned with our local market provider contracts and care delivery.

We also generally support CMS' desire to depend more on MA encounter data in calculating the cost-sharing limits and ensuring they are not discriminatory, but we continue to encourage CMS to work with MA plans to ensure data accuracy prior to moving away from the use of fee-for-service (FFS) data.

- **Recommendation: Finalize the proposal to revise the regulations controlling MA MOOP limits to incorporate new authority permitting changes in data and methodology and increasing flexibility to encourage plan offerings with lower MOOP limits.** We support CMS using the annual Call Letter process to update the MOOP and cost-sharing limits and encourage CMS to offer additional MOOP levels and increase the number of service categories.

Other MA Proposals

1. Seamless Enrollment

We support a seamless enrollment process, "whereby an individual currently enrolled in a non-MA health plan offered by an MA organization at the time of his or her Initial Coverage Election Period is deemed to have elected an MA plan offered by the organization if he or she does not elect to receive Medicare coverage in another way." Proposed Rule at 56365. We also appreciate CMS proposing to codify such a process in regulation. While we agree that seamless enrollment of Medicare beneficiaries into D-SNPs is more operationally straightforward, the statute provides this flexibility for all newly eligible Medicare beneficiaries, and we urge CMS to work with MA plans to ensure enrollees in commercial products have the opportunity to benefit from such a streamlined enrollment process.

Allowing MA plans to provide a seamless enrollment process for members transitioning to Medicare coverage would help enrollees who are satisfied with their coverage maintain similar coverage, while minimizing burden. Since these MA enrollees would have the option to opt out, they would still be able to choose another MA plan or FFS Medicare coverage if they prefer. Such a process could include appropriate communication with the beneficiary, such as an opt-out process, or opt-in as Aetna had previously established. For example, MA plans could set up an opt-in process whereby, once a beneficiary has confirmed their desire to remain enrolled with the sponsoring organization, CMS shares the necessary data to complete the enrollment. Alternatively, CMS could consider allowing plans to query the CMS eligibility system or providing this information to plans when a beneficiary becomes eligible and then, again, the beneficiary would have the opportunity to opt out. We acknowledge that these, and other, operational considerations need to be addressed, especially given the new Medicare beneficiary identification numbers, and we urge CMS to consider ways to support this process.

- **Recommendations:**

  - **Allow MA plans to provide a seamless enrollment process for all newly eligible beneficiaries.** We strongly support a seamless enrollment process for newly eligible beneficiaries into D-SNPs and recommend CMS work with MA plans to provide this option for commercial enrollees as well.

  - **Implement an outreach campaign educating beneficiaries about the seamless enrollment process and their enrollment options.** Seamless enrollment may cause beneficiary confusion. CMS should increase outreach to educate beneficiaries about seamless enrollment and the potential benefits, such as continuity of coverage.

We agree with CMS' proposal to require that CMS can only approve an MA plan's default enrollments if the applicable state approves default enrollment through its agreement with the MA plan. This proposal allows states to work with MA plans to determine the course of action that is best for some of the state's most vulnerable beneficiaries.

- **Recommendation: Finalize the proposal to condition D-SNP default enrollment on state approval, as a precursor to CMS approval.** We agree that giving states the ability to make decisions about this process is in the best interest of each state's beneficiaries. Moreover, involving states will promote coordination and improve operational consistency between state and MA plan systems.

2. Reducing the Burden of MLR Reporting

We appreciate CMS' proposals to recognize activities that improve quality for beneficiaries and remove any disincentives for MA plans to invest in fraud, waste, and abuse reduction. CMS has proposed that fraud reduction activities now be part of quality improvement activities (QIA), and this is consistent with historic comments to the ACA MLR rules that fraud reduction and prevention activities aid with patient safety, reduce unnecessary medical expenses, help produce a likely outcome, and aid in improving the quality of care. In addition, Aetna would like CMS to consider an alternative and place fraud reduction activities in the MLR numerator as a separate category, similar to mandatory and supplemental benefits. By treating fraud reduction expenses separately CMS can encourage MA plans to pay more attention to fraud reduction activities, but also may be able to more easily track, measure, and audit the allocations of such expenses to fraud, waste, and abuse activities.

In addition, we note that "fraud reduction activities" is not currently defined in regulation or statute, and we would encourage CMS to define fraud reduction activities in 42 CFR §§ 422.2430 and 42 CFR 423.2420 either under (a)(iii) regarding improving patient safety, or perhaps by even providing a separate category and describing what constitutes these activities. If CMS elects to include fraud reduction as a separate category in the numerator, as we have suggested, then CMS would then define fraud reduction activities under 42 CFR § 422.2420, calculation of the medical loss ratio (and CMS is already proposing to remove § 422.2420(b)(2)(ix) and 423.2420(b)(2)(iii) and delete from inclusion in incurred claims the amount of claims payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses), and by defining or providing some general guidance on what constitutes such activities, the industry will be more consistent in these allocations and can track such allocations in their systems.

We appreciate that CMS recognizes that limiting or excluding investments in these activities undermines efforts to combat Medicare fraud and increases costs to taxpayers and beneficiaries. To this end, we would also urge CMS to widen the definition of fraud reduction efforts to also include activities related to prevention of waste and abuse, as this is clearly a part of fraud reduction. We recommend CMS used the definitions of fraud, waste, and abuse in Chapter 21, Section 20 of the Medicare Managed Care Manual and Chapter 9 of the Prescription Drug Benefit Manual. Thus we believe it is important that CMS treat investments aimed at preventing waste and abuse in a similar manner to fraud, as already statutorily stated and as set forth in the CMS Manuals.

- **Recommendations:**
  - **Support inclusion of fraud, waste, and abuse reduction expenses in the MLR numerator as either QIA, or consider treating fraud reduction activities as a separate numerator expense for measurement and audit purposes.** Separating fraud reduction activities could help CMS ensure that the MLR calculation sufficiently captures the true nature of these activities and would result in more consistent MLR calculations across MA plans.

  - **Finalize the medication therapy management (MTM) clarification.** We appreciate CMS' clarification that MTM activities qualify as QIA expenses. We agree that these activities improve quality and should be included in the QIA portion of the MLR calculation

  - **Finalize the proposal to significantly reduce the MLR reporting requirements.** We strongly support CMS' efforts to reduce unnecessary plan burden and acknowledge that plans are still responsible for document retention and audit response. We would encourage CMS to consider similar changes to the MLR reporting requirements for commercial plans.

3. Removal of the Quality Improvement Program (QIP)

We strongly agree with CMS' proposal to remove the QIP from the MA quality improvement program. As CMS notes, we invest heavily in initiatives aimed at reducing hospital readmissions, improving care management of enrollees with chronic conditions, and other areas of care quality improvement. The removal of this requirement will allow us to focus on continuing to improve care quality and ensure that MA plans have the flexibility to look across their members and identify the areas of greatest need, instead of potentially duplicating efforts in one area.

- **Recommendation: Finalize the proposal to remove the QIP from the MA quality improvement program requirements.**

4. Compliance Program Training

Aetna appreciates CMS' acknowledging the burden of the Compliance Program Training Requirements (Training) as it relates to FDRs in §§ 422.503 and 423.504. As proposed, the removal of the CMS created web-based standardized compliance program training modules established by the May 23, 2014 final rule (79 Fed. Reg. 28844, 29853 and 29855) that created standardized training to satisfy the compliance training requirement would once again create ambiguity. Additionally, removing the reference to the FDR Compliance Training requirement from the sections of the guidance codified at §§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C), but noting that MA plans will be held accountable and tested as part of a CMS' Part C and Part D program audits to meet the Training requirements creates conflict. Overall lack of clarity of with

these changes does not address the address the concerns of providers and still places the burden on the MA plans to execute on the existing requirements.

- **Recommendation: CMS should establish the same compliance training requirements for MA and Part D as is required for providers participating in Original Medicare.**

5. Provider Burden

We offer several options for CMS to consider that could reduce provider burden in response to risk adjustment related medical record reviews.

- **Recommendations:**

  - **HHS and CMS should consider publishing a schedule for any audits for the various program audits that require medical record review.**

  - **CMS should evaluate its ability to coordinate with accreditation agencies and other entities regarding their request for medical records to minimize the requests to providers for medical records**.

  - **Modify the RADV audit process.** The current RADV process creates financial uncertainty. Modifying the RADV audit process in a way to ensure CMS provides appropriate oversight of payments to MA plans would bring about needed stability and predictability. The RADV audit process for the program needs to encompass both individual and employer group membership and to incorporate the unique features of each group into the program.

  - **Consult with the Office of the National Coordinator for Health Information Technology (ONC) to fix the interoperability challenges that are limiting providers' ability to efficiently transmit medical records from one entity to another.** Health information technology is intended to make the sharing of health information, such as medical records, more efficient. However, lack of interoperability standards or poorly enforced standards can obstruct seamless health data exchange by complicating transactions and posing additional barriers to the flow of information. To overcome this challenge, we recommend CMS consult with ONC to develop a way to more easily transmit medical records to MA plans or CMS as needed for post-payment reviews.

6. Star Ratings Program

Aetna firmly believes that the Star Ratings system and the linkage of Star Ratings to MA plan reimbursement have had a transformational effect on the MA marketplace and the health plans

that provide services to Medicare beneficiaries. The Star Ratings program has demonstrated that having a consistent, shared set of quality metrics can drive swift quality improvement across a broad population as evidenced by CMS' need to reset the cut points for a number of "topped out" measures this year. However, Aetna has long advocated for more transparency and stability in the program to allow MA plans to invest effectively in quality improvements and work hand in hand with our network providers so that quality incentives are aligned throughout the entire care continuum.

We commend CMS on committing to using notice and comment as a way to update and change the Star Ratings program moving forward and believe CMS will receive better and more comprehensive feedback as a result. CMS is in a position to leverage the Star Ratings program to continue to advance the quality of care and service provided to Medicare beneficiaries via MA, and to drive major advances in the healthcare marketplace by focusing on areas most critical to the advancement of healthcare in the US – chronic condition management, halting progression of disease, advanced illness/end-of-life care, and the delivery of these services in as close-to-the community/local retail environment as possible. We look forward to continuing to work with CMS on these important issues.

A. Existing Star Ratings Measures and Quality Improvement Incentives

We appreciate the Proposed Rule's specific comments regarding how well the existing Star Ratings measures create meaningful quality improvement incentives and differentiate plans based on quality. *See* Proposed Rule at 56377. In addition to our other comments regarding the Star Ratings program, we provide our recommendations to these topics below.

i. Opportunities to improve measures to further reflect health outcomes

Aetna does not believe that the Health Outcomes Survey (HOS) measures, particularly those regarding the improvement of physical and mental health, are measures that are designed to reflect true health outcomes of the current Medicare population. Since the Medicare population is aging, performance in these measures over the last several years has not demonstrated significant improvement, and overall the industry performance in this domain is consistent with 3 Stars. Thus, despite investments and interventions focused on improving health outcomes, it is counterintuitive that these measures would naturally be scored as improvements. We therefore believe it is important for CMS to consider how measures could better capture patient outcomes.

- **Recommendation: CMS could consider testing new Star Ratings measures that include patient-centered and patient-reported outcomes, alternative or improved patient satisfaction measures, and new outcome measure categories.** As we have previously recommended, CMS should test how to measure quality in ways that effectively capture the patient perspective and experience. We support testing measures to build an

evidence base that can help MA plans focus on improving true quality.

We also continue to suggest that CMS consider segmenting the measures to capture both clinical outcomes and patient experience and access measures in the areas of highest importance to beneficiaries and the health care system. MA plans primarily serve age 65+ beneficiaries, and the quality measures within the Stars program should have relevance to the issues facing that population and the quality of care measures most critical to an aged and aging population. These measures should be identified and developed with meaningful input from the patient population, and could include but are not limited to:

- Advanced illness/palliative/end-of-life;
- Multiple comorbidity outcome management;
- Limiting progression of disease for impactable conditions;
- Keeping individuals in-home and in-community.

In addition, we recommend that CMS reevaluate certain measures where MA plans consistently perform well. For example, most plans perform very well on the Diabetes Care – Kidney Disease Monitoring measure, having a spread of cut points between 1 and 5 Stars that is only about 6% (between 92%-98%). Most Part D plans perform well on the MPF Price Monitoring measure as well. Having cut points across such a small range – especially when the range reflects high performance – skews the Star Ratings in a manner that does not adequately reflect how well plans are performing. We do not believe that this type of clustering is in line with the Star Ratings program's goals of measuring quality accurately.

- **Recommendation: Reevaluate and retire measures where MA and Part D plans are typically performing so well that the cut points do not vary enough to reflect meaningful difference in quality.** We ask CMS to reevaluate the following measures:

  - Part C: Diabetes Care – Kidney Disease Monitoring
  - Part C: Adult BMI Assessment
  - Part D: MPF Price Monitoring

We also believe that CMS should invest resources in improving CAHPS measures. MA plans and contracts serve millions of beneficiaries, yet only a very small proportion of beneficiary voices are heard when it comes to patient experience measures in the Star Ratings program via CAHPS. Piloting survey instruments and measures that collect broad-based responses will provide a more accurate and credible view on the experiences of beneficiaries within MA products. In addition to response sample size concerns, the timing of the CAHPS survey administration can lead to significantly variable results. This is particularly true for surveys done early in the year.

Furthermore, the survey measures should be based on a member's actual experience with the plan, rather than provider behavior. Practices vary across provider offices, and plans have little control over the operations of provider offices, which vary widely. Basing the survey measures on plan experience, and not provider behavior, would more accurately reflect a member's experience and help ensure a more level playing field when evaluating plans.

- **Recommendation: Invest resources in improving CAHPS measures.** CMS could improve the usefulness of CAHPS measures by:

  - testing the survey timing to measure the bias introduced under the current CAHPS method;
  - better targeting the survey to capture patient experience, for example, within 30 days of a patient's last visit;
  - piloting survey administration methods that allow for broader-based collection of beneficiary responses and insights;
  - considering how to provide individual-clinician-level collection and real-time feedback to providers and plans to support them in their improvement activities; and
  - measuring areas of care that are of highest importance to beneficiaries and that are based on members' actual experience with the MA plan, instead of with the provider (e.g., such as ease of enrollment, health plan assistance in educating around plan benefits and providers, provider/plan integration to support ease of beneficiary healthcare navigation and access, and care coordination).

ii. Adjustments to account for geographic and provider market characteristics

Geographic areas and provider markets have unique characteristics that affect performance. Research shows that, particularly for medication adherence, certain regions of the U.S. consistently underperform for complex reasons. While socioeconomic status is one variable that directly correlates to underperformance, other factors, such as provider efficiency, contribute as well. CMS could review critical access area data, metro area data, and micro area data to help determine what the adjustment factors should be. We also ask CMS to look at member-level data CMS collects to determine if factors other than socioeconomic status contribute to poor performance, and to make adjustments based on this information. Alternatively, CMS could leverage the case mix adjustment process already used for the CAHPS surveys, which considers many of this factors mentioned above, and apply it to the rest of the Star Rating measures.

- **Recommendation: Adjust the Star Ratings to account for variables that contribute to underperformance in certain geographic areas by applying the case mix adjustment process currently used for the CAHPS survey.** Accounting for these variables could help create a more level playing field in the Star Ratings program.

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iii. Measuring the Adoption of New Technology and Beneficiary Experience

We appreciate CMS taking the initiative to consider adding measures that evaluate quality from the perspective of adopting new technology, such as telemedicine, and we agree that measures aimed at improving ease, simplicity, and satisfaction of beneficiary experience with a MA plan are the ideal way to measure performance. As CMS considers new measures, we recommend that CMS follow its existing process of testing new measures and previewing them as display measures prior to adoption.

- **Recommendation: Consider adding new measures aimed at adopting new technology (specifically telemedicine) and beneficiary experience. Follow the current process of testing new measures and previewing them as display measures before adopting them.**

iv. Survey Measures for Physicians' Experiences

Aetna is committed to working with its provider partners to ensure that care is delivered in a way that best serves its members. While we seek and value provider feedback through contracting and other interactions, we are concerned that including measures that survey providers on their experience with health plans would create an un-level playing field, especially because a number of MA organizations own the providers who would be responding. In addition, this change could cause contracting incentives to shift to scoring, instead of quality of care. We therefore believe this change would move the Star Ratings program away from its focus on beneficiary impact and outcomes.

- **Recommendation: Focus survey measures on the members, and seek provider feedback through other avenues.** Keeping the surveys focused on members would ensure that incentives remain focused on member experience and health outcomes, which is the ultimate goal of the Star Ratings program. CMS could seek provider feedback through other types of communication outside of the Star Ratings program.

B. Contract Ratings and Reporting Levels

We welcome the opportunity to comment on how CMS can calculate Star ratings at different levels other than the contract level (e.g., parent organization, contract, plan, or geographic area). Since changing the system could create undue administrative burden and volatility, we believe it is crucial for CMS to engage an industry-wide working group to discuss what changes should be made and how to address operational challenges. Until the working group has proposed changes and those changes have gone through the notice and comment process, Aetna believes that CMS should maintain the current system in place to ensure that the Star Ratings program does not add undue administrative burden, provider abrasion, or

sample size volatility into the MA quality environment. Any changes with more granular reporting levels would significantly increase administrative burden on MA plans, and provider burden would increase as well, since HEDIS medical record and data collection activities would expand markedly across the industry.

- **Recommendation: Establish an industry-wide working group to discuss potential changes and operational challenges, and propose any changes via the notice and comment process.** We are committed to working with CMS to help establish a reporting process that is the most efficient and effective.

C. Consolidated Contracts

Aetna generally supports CMS' proposal to establish a Star Rating methodology for consolidated contracts that leverages an enrollment-weighted average of surviving and consumed contracts' performance. We agree that this process will more accurately reflect performance and ensure that contract consolidations are not occurring as a mechanism to increase Star Ratings. We also appreciate CMS recognizing that contracts operated by the same parent organization are likely to share many administrative process and procedures.

- **Recommendation: Finalize this proposal.**

D. Adding, Updating, and Removing Star Ratings Measures

Aetna agrees with CMS' proposal for adding, updating, and removing Star Ratings measures. We believe that providing as much transparency into the process in advance of the measurement period will allow plans to align providers, vendors, and investments appropriately.

- **Recommendation: Finalize this proposal.**

E. Data Integrity

We support CMS using a scaled approach to reduce the measure-level Star Ratings when a data integrity issue is found, and we agree with the additional proposed criteria for the reduction. However, we ask CMS both to clarify what is determined to be a data integrity issue and to give plans an opportunity to discuss any finding of a data integrity issue with CMS as needed.

- **Recommendation: Provide a clearly-defined framework to communicate what CMS will consider a data integrity issue and when scaled reductions will take place. In addition, provide plans with the opportunity to communicate with CMS regarding any reduction in Star Ratings that is the result of a data integrity issue.** While we

agree with the general approach, we believe it is important for plans to understand what problems could trigger any type of reduction and to have an opportunity to discuss issues with CMS in order to make improvements.

F. Measure-Level Calculation Changes

While we continue to believe CMS should set cut points prospectively, Aetna greatly appreciates CMS' consideration of guardrails on the variability of the cut points year over year. We ask CMS to establish a cut point process that limits fluctuations across measures and recommend that CMS use its own Quality Improvement thresholds to establish these guardrails. It is critical that MA plans and providers maintain strong partnerships as they collaborate to provide the best care for beneficiaries. However, large swings in cut points year-over-year create instability, and, therefore, dissatisfaction among the provider community. Aetna supports a process where CMS looks across several years of performance and establishes guardrails within each measure, to ensure more stability and predictability in the cut points.

- **Recommendation: Base cut points on several years of performance and establish guardrails to minimize annual fluctuations.** Specifically, we recommend that CMS pull forward their own definitions of significant change from the Health Plan Quality Improvement measure to act as the guardrail for the measure, and that the changes in cut points year-over-year do not exceed these thresholds. For comparison, HEDIS measures generally demonstrate significant change between 3-4%, and Patient Safety measures demonstrate significant change between 2-3%. We ask CMS to use these measures as a baseline to determine the definition of significant change for the Health Plan Quality Improvement measure.

Aetna strongly disagrees with CMS' proposal to increase the weighting of the CAHPS measures. The Star Ratings are linked to process, access, and outcomes; of these categories, we believe that clinical outcomes are the most important category because they truly reflect member health. However, most of the CAHPS measures are based on access issues, not clinical outcomes. Therefore, increasing the weighting of the CAHPS measures would dilute the measures focused on outcomes, which would be counterintuitive to the goals of the Star Ratings program.

- **Recommendation: Maintain the current weighting of CAHPS measures, which is at 1.5.** We believe that, since these measures are access-based measures, they are currently weighted appropriately. A higher weighting of CAHPS measures would dilute the outcomes-based measures and undermine the goal of the Star Ratings program.

7. Marketing

A. Electronic Delivery

CMS' proposals regarding marketing requirements are positive changes that will help MA plans operate more efficiently and communicate with beneficiaries more effectively. We strongly support CMS' proposal to allow MA plans to provide some beneficiary communications, including the Evidence of Coverage (EOC), electronically. This change is cost-efficient, and MA plans could use these saved resources for other benefits. In addition, we believe many beneficiaries would welcome receiving information electronically. Studies have shown that the Medicare population has become increasingly well-versed in electronic communications. (*See* PwC, Top health industry issues of 2018 A year for resilience amid uncertainty, available at: PwC: https://www.pwc.com/us/en/health-industries/assets/pwc-health-research-institute-top-health-industry-issues-of-2018-report.pdf (stating that "older adults are increasingly willing to use digital health services")). Therefore, we agree that electronic delivery should be allowed as the default delivery method for the EOC.

We recognize that some members would prefer to receive hard copies of these materials. For those members, we recommend that members request paper copies by calling the MA plan.

- **Recommendations:**

  - **Finalize the proposal to enable MA plans to disseminate the EOC documents electronically, and allow members to call the MA plan to request paper copies of these documents if they choose to do so.** A process such as this would create efficiencies, while also ensuring that members receive these materials in a manner that is the most useful for them.

  - **Finalize the proposal as soon as possible.** We also ask that CMS finalize this proposal as soon as possible, so plans have enough time to implement these changes for the next annual election period (AEP).

B. ANOC/EOC Timing Change

We also support the proposal to change the requirement to provide an EOC by the first day of the AEP instead of 15 days before the AEP. We agree that separating the timelines for delivering the EOC from the ANOC helps minimize beneficiary confusion and gives plans more time to ensure the EOC contains accurate information.

- **Recommendation: Finalize this proposal.** This change would maximize the accuracy of the EOC and reduce beneficiary confusion by allowing them to focus on the ANOC (i.e., the decision-making document) first.

C. Prohibition on Marketing During OEP

We welcome the opportunity to comment on how CMS should implement the 21st Century Cures Act's prohibition on unsolicited marketing and mailing marketing materials to eligible individuals during the Open Enrollment Period (OEP). *See* Social Security Act (the Act) § 1851(e)(2)(g)(iv). While the Act, as amended, prohibits certain types of marketing during OEP (e.g., at health care settings and educational events), it directs the Secretary to establish other marketing limitations. We agree that a flat prohibition on marketing during OEP would be too broad, but we also believe the proposal for a "knowing" standard is not appropriate. *See* proposed 42 CFR §§ 422.2268(b)(10) and 423.2268(b)(10). This standard would unfairly disadvantage MA plans where a beneficiary might already be enrolled, since that plan would be more likely to know that the enrollee was enrolled in an MA plan during the previous year. If another MA plan does not know that enrollees are already enrolled, that MA plan could market to those enrollees, potentially influencing enrollees to switch plans. This standard would not be in the best interest of beneficiaries and could cause market disruption.

- **Recommendation: Create a standard where marketing during OEP is not targeted to specific enrollees, thus plans would be permitted to run general marketing campaigns (plan-specific or on the MA and/or Part D program).** This type of standard would satisfy statutory requirements, would reduce beneficiary confusion, and would ensure that plans are on a level playing field.

D. Streamlined Requirements

Finally, we appreciate CMS' attempts to streamline requirements for marketing materials by separating the definitions of "marketing" and "marketing materials" from the definitions of "communications" and "communication materials." We agree that marketing materials should be those that are intended to influence a beneficiary's decision-making process when choosing an MA plan, and we support the proposed regulation language listing the types of materials that would be considered marketing materials. While this is a positive development, we also note that much of the burdensome marketing requirements are not regulatory but rather appear in the Medicare Marketing Guidelines. Therefore, we ask CMS to also streamline the requirements for marketing materials in the Medicare Marketing Guidelines.

- **Recommendation: Finalize the proposal to limit what materials constitute marketing materials (i.e., those intended to influence enrollment in an MA plan), but also streamline the requirements for marketing materials beyond this regulation, such as in the Medicare Marketing Guidelines.** While the Proposed Rule proposes promising changes, revising the requirements in the Medicare Marketing Guidelines would further help improve efficiencies and clarity for beneficiaries.

8. Physician Incentive Plans

We appreciate CMS' responsiveness to industry requests for updates to the Physician Incentive Plan (PIP) rules. While we strongly agree that the stop loss insurance limits are overdue for an update to better account for medical costs and utilization changes since the final rule was released in 2000, we believe that some of the proposed changes further complicate, rather than simplify, the PIP rules. Further, some of the assumptions on which these proposed rules are based signal that CMS may be building its regulatory framework without the benefit of a completely up-to-date understanding of the value based models and arrangements prevalent in the industry today. While we applaud CMS' efforts to revisit the PIP regulations, we would recommend that CMS institute a working group with MA plans and possibly physician stakeholders, to discuss in detail the various arrangements pursued in today's marketplace and the pain points remaining in the PIP rules. We believe that one of the most important aspects of the regulation is that it needs to be simple and easy for physicians and physician groups to understand. We share CMS' interest in protecting beneficiaries and feel that together we can work to devise a means of protecting beneficiaries and physicians in a more efficient and simplified manner.

A. Revised Deductible Limits

We strongly agree that the stop-loss deductible limits at § 422.208(f)(2)(iii) were in need of updating, and we are in favor of CMS codifying the methodology by which it will update the stop-loss deductible limits in the future to account for changes in medical cost and utilization. With regard to frequency of updates to the prescribed deductible table, we believe updating every three years would be adequate. However, we do have some concerns regarding the methodology proposed for calculating attachment points, and the assumptions upon which the proposed methodology is based. First, the proposed regulations explain that in calculating the stop loss deductible limits CMS used "projections of total income based on services provided personally by individual physicians and directly by physician groups because that is how we interpret 'potential payments' as defined in the existing regulation." Proposed Rule at 56462. We read the current definition of "potential payments" to include not only the maximum payments possible for services provided personally by physicians/physician groups but also to include payments based on the use and cost of referral services such as bonuses, capitation, or other compensation. We question whether CMS' narrower interpretation of potential payments may have skewed the calculation of deductible limits inappropriately to a lower or more conservative than necessary number. Also, in response to CMS' request for comments on whether the description of the methodology provided is sufficient, we do not feel that there is enough information in the proposed rules to fully evaluate the proposed methodology. We ask that more detail be provided including a detailed calculation for one of the cells in the table. Further, given the complex nature of the methodology for setting attachment points, we recommend that CMS seek input on its proposed methodology from American Academy of Actuaries.

Additionally, our understanding is that stop loss policies with no limits on coverage are rare in the commercial marketplace and possibly non-existent. We believe that the regulation needs to account for this limitation, so that physicians can shop for coverage from third parties rather than having to rely on the MA plans themselves to supply coverage or apply caps. Finally, we note that the proposed regulations specifically note that the newly devised deductible limit tables at Table 13 and Table 14 of the proposed regulations are to be used only in instances of capitated risk, and that other stop-loss insurance types must to be used for non-capitated arrangements. We ask CMS to clarify its intent, as it is not clear what other stop loss insurance would be required in non-capitated situations where a physician/physician group is at substantial financial risk under the regulations.

Our final suggestion, made with simplicity and ease of implementation in mind, would be to revise the deductible limit tables to utilize the same groupings of panel sizes that are found in the current regulation (just instituting the higher deductible amounts now proposed) and the same structure for separate institutional and professional deductibles should be carried into the new regulation. We feel the method described in the proposal for calculating separate institutional and professional deductibles is too complicated for physicians to understand.

B. Actuarially Equivalent Arrangements

We are generally in favor of the idea of CMS granting MA plans and Physicians/Physician Groups increased flexibility to devise protections specific to their particular PIP arrangements. While we appreciate CMS providing flexibility in allowing plans to develop alternative methods of complying with the regulation, we feel that more guidance is needed to understand how CMS would define actuarially equivalent in the context of the regulation. For instance, could an MA plan devise an actuarially equivalent arrangement only in certain types of arrangements, such as those non-capitated arrangements for which the proposed rules state that Tables 13 and 14 would not apply? The current proposal does not provide enough guidance to permit our actuaries the confidence to take advantage of the intended flexibilities.

C. Non-Risk Patient Equivalents

We strongly agree that the number of a physician group's non-risk patients should be taken into account when setting stop loss deductibles for risk patients. However, we feel the proposal is far too complicated to be practically applied. Since MA plans only have access to information on our members for a physician, it is critical that the regulation provide a method that can be simple enough to be determined by the physicians themselves and the data required to validate it not be proprietary, such that it can be shared with the MA plans. This same difficulty exists in the current regulations when applying the pooling rules MA plans face substantial difficulty verifying a physician's panel size and that the pooling rules are being accurately applied, as we often do not have complete information on the arrangements that a physician has with its other payers, as those arrangements are proprietary and generally

made confidential between parties thereto. Accordingly, we believe that stop loss deductibles should be determined by total physician revenue for a recent past period and/or total patient count defined in a very simple manner such as unique patients that the physician provided services to in a recent past period.

D. Other Comments

We note in the proposed rules several instances where CMS states the MA plan must "provide" stop-loss protection. Under the current regulations and sub-regulatory guidance, our understanding is that an MA plan must ensure that the physician/physician group at substantial financial risk has in place the required stop loss coverage. We seek confirmation from CMS that this is still the case and that the MA plan is not required to pay for, or provide on its own or through a third party, such stop loss insurance.

9. Elimination of Medicare Advantage Plan Notice for Cases Sent to the Independent Review Entity (IRE)

We strongly support CMS removing the requirement for an MA plan to mail a notice to an enrollee when the enrollee's case is forwarded to an IRE. We agree that this requirement is duplicative, since the IRE notifies the enrollee that it has received the enrollee's case.

- **Recommendation: Finalize the proposal to eliminate this requirement.**

10. Reducing Past Performance Review Period for Applications Submitted by Current MA Plans

Aetna agrees that CMS should shorten the length of the past performance review period from 14 to 12 months when determining whether an MA plan has failed to comply with certain contracting requirements. We believe a 12-month look-back period is adequate for existing MA plans, especially because 12 months aligns with the application review cycle and is the length of a contract year.

- **Recommendation: Finalize a 12-month look back period to review past performance for applications submitted by current MA plans.**

Medicare Part D Provisions

1. Any Willing Pharmacy (AWP)

We appreciate CMS' desire to clarify the AWP requirements and ensure that pharmacies able and willing to meet a Part D sponsor's standard terms and conditions (ST&C) and reimbursement rates are able to participate; however, we are concerned that CMS' proposals will create additional confusion, be burdensome, and ultimately result in higher costs and less quality control.

We are also concerned that the agency's proposed interpretations raise questions about the scope of CMS' authority to regulate Part D sponsor relationships with pharmacies. *See* the Act § 1860D-11(i) (prohibiting CMS from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and PDP sponsors."). We believe the current AWP guidance is sufficient and recommend CMS conduct a rigorous analysis to determine whether impermissible barriers to participation in plans by AWPs actually exist, rather than relying on anecdotes.

In the Proposed Rule, CMS' proposed definitions of "mail order" and "retail" pharmacies will allow pharmacies to define themselves as either, creating significant beneficiary confusion over whether a particular prescription drug is subject to mail order or retail cost sharing. Further, in the Proposed Rule, CMS "clarifies" that "similarly situated" pharmacies include any pharmacy *able* to comply with the ST&Cs for a pharmacy type, regardless of whether the pharmacy operates exclusively as that type. This clarification encourages pharmacies to agree to different ST&Cs because the rates are better, even if it may be difficult for the pharmacy to meet the ST&C and even if the pharmacy cannot meet the necessary beneficiary safety requirements.

Finally, we are very concerned about CMS' discussion of accreditation requirements and waivers of a specific ST&C. In some cases, Part D sponsors must pay certain pharmacies higher prices because those pharmacies are necessary to ensure that the Part D sponsor meets the network adequacy standards. In fact, existing CMS guidance recognizes that deviation from standard terms may be required for such reasons – "[i]t is unlikely that a Part D sponsor could establish a network using a uniform set of terms and conditions throughout a service area because it will likely need to modify contracting terms and conditions to ensure access to certain pharmacies – for example, rural and long-term care pharmacies." (Prescription Drug Benefit Manual, Ch. 5, § 50.8.1) Rural or high-cost areas may justify higher reimbursement rates for pharmacies in those areas, but the existence of these areas does not justify higher reimbursement rates for **all** pharmacies. In these circumstances, forcing plans to offer higher payment rates to all network pharmacies, when most pharmacies have agreed to receive lower payment rates, would certainly increase costs and is an inefficient use of taxpayer money. We expect that the result of this proposed change will not be the price savings and greater availability predicted by CMS, but instead will be less favorable pricing to Part D sponsors, which will lead to higher premiums for beneficiaries and increased costs overall for the Part D program.

Finally, it is critical to note that Part D sponsors use networks to ensure the pharmacies offered to the plan's beneficiaries meet the plan's standards, including quality criteria, as well as to negotiate volume discounts. In fact, performance on many of the Star Ratings measures is affected by the pharmacy network, and Part D sponsors take seriously their responsibility to ensure that their contracted pharmacies adhere to network standards. The AWP proposal threatens Part D sponsors' ability to impose standards on participating pharmacies, and therefore threatens to erode the quality of services provided to beneficiaries. Along those lines, accreditation requirements are designed to ensure beneficiary safety and are a critical piece of any ST&Cs.

While unique circumstances that require a waiver may arise, there is no clinical reason to remove those protections from the broader network.

- **Recommendation**: **CMS should reconsider whether new AWP guidance is necessary and engage in a comprehensive analysis of the issues raised in this notice and comment process to determine the scope of the problems and how best to resolve them.** We remain very concerned that many of these changes are the result of anecdotal evidence and that they will increase beneficiary confusion and programmatic costs. Further, we believe they will limit the autonomy of Part D sponsors to negotiate and create their own networks to address the specific needs of their enrollees and to ensure beneficiary safety.

2. Codification of Part D Tiering Guidance

We ask CMS to clarify how it expects to treat a situation where the lowest cost-sharing exception to a tier 4 drug is a specialty tier drug or biological. Most Part D sponsors limit specialty tier supply amounts to a 30-day supply (as opposed to a 90-day supply for drugs on other tiers). If a member receives an exception and receives a specialty tier drug instead of a tier 4 drug, we believe CMS should still allow Part D sponsors to fill the drug in 30-day increments.

We understand that CMS is not proposing to modify the current guidance on treatment of non-formulary drugs approved for a formulary exception and thus we also ask CMS to confirm that these drugs would continue to be ineligible for additional tiering exceptions.

- **Recommendations:**

  - **Clarify that if a member receives an exception from a tier 4 to a specialty tier drug, Part D sponsors are able to retain any supply limits in place for the tier on which the Part D sponsor has placed the drug the member is receiving.**

  - **CMS should confirm that tiering exceptions for non-formulary drugs approved for a formulary exception continue to be not eligible for additional tiering exceptions, consistent with current CMS guidance.**

3. Mid-Year Formulary Changes

We support CMS' proposal to allow generic substitutions and to change formularies mid-year, as long as Part D sponsors provide upfront notice to beneficiaries that these changes are possible. As CMS is aware, certain drugs are released and approved mid-year, and giving Part D sponsors the option to make mid-year formulary changes would ensure that the Part D program is running as efficiently as possible.

- **Recommendation: Finalize this proposal.**

4. Part D Enhanced Alternative Plan Offerings

We support CMS in its intent to reexamine how to define meaningful difference between basic and enhanced plans offered by the same Part D sponsor within the same service area. As noted in our comments regarding MA meaningful difference, we believe Part D sponsors should have as much flexibility as possible. We therefore believe that CMS should eliminate the current out-of-pocket cost (OOPC) model and give plans more flexibility to create options that best serve their members.

- **Recommendation: Eliminate the OOPC meaningful difference requirement on enhanced alternative benefit designs offered by the same organization in the same region.**

5. Changes to the Days' Supply Required by the Part D Transition Process

We strongly support CMS' proposal to shorten the required transition days' supply in the long-term care setting to the same number of days required in the outpatient setting. We agree that a transition period for a Part D beneficiary in a long-term care setting is not any longer than a transition period for a Part D beneficiary in an outpatient setting. We also strongly support CMS making a technical change to clarify CMS' intent that the required outpatient supply for a transition fill be one month.

- **Recommendation: Finalize these proposals.**

6. Treatment of Follow-On Biological Products as Generics for Non-Low-Income Subsidy (LIS) Catastrophic and LIS Cost Sharing

We appreciate CMS revisiting the treatment of follow-on biological products and determining that they should be treated as generics for the purposes of non-LIS catastrophic and LIS cost sharing. We agree that the treatment of biosimilar biological products as brands for purposes of LIS cost sharing creates a disincentive for LIS enrollees to choose lower-cost alternatives, and we agree that similar concerns arise for non-LIS catastrophic enrollees.

- **Recommendation: Finalize the proposal to treat follow-on biological products as generics for non-LIS catastrophic and LIS cost sharing.**

7. Limitations for the Part D Special Election Period for Dual-Eligible Beneficiaries

We support CMS limiting the Part D special election period for dual-eligible beneficiaries to apply to certain circumstances. We agree that a more limited special election period will not hinder plan

choice or continuity of care for duals, and it could in fact improve continuity of care for these beneficiaries.

- **Recommendation: Finalize this proposal.**

8. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations

Aetna agrees that CMS should change the adjudication timeframe for Part D standard redetermination requests for payment from the current requirement of seven calendar days to 14 calendar days. We agree that allowing Part D sponsors and IREs to issue and effectuate redeterminations in favor of enrollees within 14 calendar days creates consistency across Part D appeals processes and reduces administrative burden by ensuring the decisions are as fully informed as possible.

- **Recommendation: Finalize the proposal to lengthen the adjudication timeframe for Part D sponsors and IREs.** As CMS states, this longer timeline would ensure that the decisions are as fully informed as possible and would create consistency across appeals processes.

Preclusion List for MA and Part D

We would like to commend CMS for proposing to withdraw the burdensome provisions in § 422.222 and § 423.120(c)(6) that require eligible providers and suppliers to enroll in (or in the case of Part D validly opt-out of) Medicare in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA plan. As we have expressed on numerous occasions, we remain concerned that allowing these provisions to go into effect will result in significant access issues and beneficiary confusion, not to mention increased administrative costs, while not significantly reducing waste and abuse in the programs. However, despite our serious concerns regarding the operational challenge of enrolling prescribers that are not "typical" Medicare providers, we are even more concerned about the establishment of a new "preclusions" list.

Aetna supports CMS' goal of ensuring that only clinically appropriate prescriptions are covered and understands the need to protect beneficiaries from suspicious and inappropriate care patterns. Today, MA plans and PBMs rely on the Office of the Inspector General's (OIG) List of Excluded Individuals/Entities ("OIG exclusion list") and the General Services Administration's (GSA): Compilation of Federal Procurement Debarred Individuals to prevent payment of inappropriate claims. We are also strongly supportive of new initiatives aimed at reducing inappropriate care, such as the implementation of the CARA provisions, as discussed elsewhere in this rule.

As proposed, the new preclusions list would overlap and include additional providers not on the

OIG or GSA exclusion lists, creating additional operational and administrative challenges. For example, it is unclear how the two lists interact and what happens when a provider is on both, including but not limited to the provisional Part D fill requirement. Further, most beneficiaries understand that if a provider or supplier has been excluded from receiving payment from all Federal programs, their services cannot be covered by Medicare. Explaining to a beneficiary that a case-by-case determination has been made that their provider is not eligible for Medicare payment is very confusing and more likely to result in a beneficiary not receiving necessary treatment than the prevention of fraud.

- **Recommendation: Finalize the proposal to rescind the enrollment provisions at § 422.222 and § 423.120(c)(6) and, in addition, rescind the requirement for a 90-day provisional fill.** Alternatively, if CMS continues to believe the proposed preclusions list is necessary, Aetna believes CMS should reconsider how to best implement the enrollment provisions and provide a longer lead time.

CARA and Addressing the Opioid Epidemic

We support CMS' continued efforts to address the opioid epidemic and believe the implementation of CARA, and the adoption in Part D of a lock-in mechanism, will provide Part D sponsors with a critical tool to help curtail inappropriate abuse of opioids and other medications. Further, we appreciate CMS efforts to integrate the CARA drug management provisions with the current Part D Opioid DUR policy and OMS. We also agree that opioids should be the initial focus of the new lock-in function; however, as noted in our recommendations below, Part D sponsors should retain the ability to include other frequently abused drugs, as they do with their current point-of-sale (POS) claims edits. We discuss this and other recommendations below and appreciate the opportunity to comment on the implementation of CARA.

1. Clinical Guidelines

We agree with the clinical guideline CMS has proposed to use in drug management programs: Use of opioids with an average daily MME greater than or equal to 90 mg for any duration during the most recent 6 months **and either**: 4 or more opioid prescribers and 4 or more opioid dispensing pharmacies **or** 6 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. *See* preamble to the Proposed Rule at 56345. In addition to the proposed clinical guideline, we recommend that CMS add an additional clinical guideline that would allow Part D sponsors to lock in an at-risk beneficiary if they meet the second criteria, regardless of the average daily MME amount. Receiving opioid prescriptions from multiple prescribers and pharmacies is a serious care coordination issue and puts beneficiaries at risk for unintentional abuse even at lower MME levels.

Further, we have found through communication with providers, during opiate case management, a desire on their part to have these types of restrictions implemented as part of their effort to help control the behavior of high-risk members. This type of request has on occasion occurred with

members who would not necessarily meet the MME criteria. Additionally CMS does provide safety data through Acumen regarding members utilizing a high number of pharmacies and prescribers independent of MME. The POS edit and proposed lock-in can be valuable tools when addressing outliers. This type of lock-in would help prescribers take a leading role in coordinating a beneficiary's care and identify situations of concern.

- **Recommendation: Establish additional clinical guidelines to include situations where a:**

    - **beneficiary is receiving opioid prescriptions from 4 or more opioid prescribers and 4 or more opioid dispensing pharmacies or 6 or more opioid prescribers (without meeting an minimum average daily MME amount); or**
    - **prescriber requests a POS edit or lock-in to help them with care coordination of a beneficiary.**

We understand CMS wanting to limit the new lock-in mechanism to opioids initially and to allow CMS and stakeholders to gain experience before considering adding additional non-opioid clinical criteria. However, Part D sponsors have long used POS edits as a means to address opioid and non-opioid medication abuse. For example, plans may use POS edits to prevent concurrent abuse of opioids and benzodiazepines or address non-opioid drug abuse. Part D sponsors also have significant experience with using CMS requirements as a floor for establishing POS safety edits. As noted above, a provider could be aware of a particular piece of information placing the beneficiary at risk and could communicate with the Part D sponsor to place a POS edit on the beneficiary's opioid prescriptions. In these situations, the beneficiary may not meet the minimum clinical guidelines for a required POS edit. We are concerned that CMS is taking away an important tool for protecting beneficiary safety in an attempt to integrate the current programs with the new lock-in tool.

- **Recommendations:**

    - **Maintain Part D sponsors' ability to develop broader clinical criteria for establishing POS edits for at-risk beneficiaries.** We ask CMS to preserve Part D sponsors' ability to maintain as much flexibility as possible when creating POS edits for at-risk beneficiaries under certain circumstances.

    - **Allow Part D sponsors to continue to implement current policy for non-opioid medications.**

2. Beneficiary Notification

Currently, Part D sponsors are able to place a full block on an opioid prescription and provide notice to prescribers and beneficiaries within 30 days. As CMS knows, CARA has changed notice

requirements to include both an initial and second notice, requiring that a second notice shall be provided to the at-risk beneficiary no less than 30 days after an initial notice is provided to the beneficiary. However, CARA also creates an exception for a Part D sponsor to provide a second notice on an earlier date if the Part D sponsor "in conjunction with the Secretary, determines that concerns identified through rulemaking by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the PDP sponsor to provide a second notice . . . to the beneficiary on a date that is earlier than [30 days]." Act section 1860D-4(c)(5)(B), as added by CARA section 704(a). A shorter timeframe between initial and second notices would help Part D sponsors and prescribers capture a greater number of at-risk beneficiaries.

- **Recommendations:**

  - **CMS should allow Part D sponsors to provide the second notice within 15 days of the initial notice.** Limiting the timeframe between initial and second notices will help capture a greater number of at-risk beneficiaries and will likely prevent some of those individuals from facing addiction.

  - **CMS should maintain the one notice requirement when Part D sponsors implement POS edits, consistent with current policy, rather than add a second notification and delay implementation.**

3. Exceptions

The Act, as added by CARA, exempts certain individuals from the definition of at-risk beneficiary: (1) an individual who receives hospice care; (2) and individual who is a resident of a long-term care facility; or (3) and individual whom "the Secretary elects to treat as an exempted individual." Act section 1860D-4(c)(5)(C) (ii). The Proposed Rule's proposal to exempt individuals with cancer diagnoses is too broad of an exclusion. In rare circumstances, we have experienced situations where providers have asked Part D sponsors to place POS edits on beneficiaries with non-terminal cancer who are abusing opioids. We therefore believe that a cancer diagnosis alone should not be reason enough to exempt someone from being considered an at-risk beneficiary and receiving intervention he/she needs to prevent or stem opioid addiction.

- **Recommendation: Exclude individuals with active, malignant cancer from the definition of at-risk beneficiaries, and implement this requirement on a case-by-case basis through conversations between the Part D sponsor and the prescriber.** Narrowing the exemption for individuals with cancer would strike the appropriate balance between ensuring beneficiaries have access to drugs when needed and preventing opioid addiction among certain individuals. We also believe the care management requirement should help ensure that beneficiaries are appropriately excluded and included.

4. Maximum Duration of Lock-In Period/POS Claim Edit

We urge CMS not to finalize its proposal to have the definition of at-risk beneficiary terminate at the earlier of (1) the date the beneficiary demonstrates that he/she is no longer likely to be at risk; or (2) the end of a 12-month period. While CMS notes that the coverage limitation may go beyond 12 months if a beneficiary meets the clinical guidelines, and a Part D sponsor implements an additional, overlapping limitation on access to drugs, we do not believe a Part D sponsor should have to implement additional limitations to extend this definition. A 12-month maximum period places beneficiaries at greater risk of addition or relapsed addiction.

We acknowledge that CARA provides for termination of at-risk status if a beneficiary "demonstrates that he or she is no longer likely to be an at-risk beneficiary in absence of limitations." Proposed Rule at 56359. We believe that providers are in the best position to determine when a beneficiary is no longer at risk of opioid addiction, and CMS should defer to the expertise of professionals who are familiar with each beneficiary's situation. If a beneficiary requests to have their at-risk status changed, sponsors are only able to look at the claims filled prior to and during the lock-in period. Especially for stand-alone Part D plans, the lock-in mechanism results in a non-concerning prescription claims patterns. Sponsors must depend on prescribers to provide evidence that the beneficiary is no longer at-risk without these limits. We believe enabling Part D sponsors to depend on providers to determine when to lift limitations would lead to a lower recidivism rate.

- **Recommendation: Instead of setting a concrete time limit, CMS should allow Part D sponsors to keep the limitation on at-risk beneficiaries until the Part D sponsor is notified by the applicable provider(s) that the beneficiary is no longer at risk.** Alternatively, CMS could consider requiring Part D sponsors to send annual notifications to locked-in beneficiaries and their approving prescribers to let them know the lock-in will be extended the following 12 months. This would afford beneficiaries and prescribers an annual opportunity to request that the lock-in be reconsidered or raise any concerns.

5. Limitation on Special Enrollment Period

We support the proposal that the initial notice to potentially at-risk beneficiaries also notify dually- and other LIS-eligible beneficiaries that they will be unable to use the special enrollment period for LIS beneficiaries (duals SEP) because they are at risk. We agree that removing the duals SEP would prevent at-risk LIS-eligible beneficiaries from switching plans and either moving to a Part D sponsor without a drug management program, or being able to access opioids because of a gap in information sharing across plans. We believe this proposal would help curb opioid abuse in this vulnerable population.

- **Recommendation: Finalize this proposal.**

6. Coverage Determinations

CMS proposes that determinations for at-risk beneficiaries made under drug management program processes (*see* § 423.153(f)) be adjudicated under the existing Part D benefit appeals process and timeframes (*see* 42 CFR 423 subpart M). However, the Proposed Rule explicitly states that, instead of revising the existing definition of a coverage determination (*see* 42 CFR § 423.566), which discuss coverage or payment for a drug based on whether it is medically necessary, CMS will cross reference § 423.153(f) in relevant provisions in subparts M and U. CMS also states that, "[w]hile a coverage determination made under a drug management program would be subject to the existing rules related to coverage determinations, the other types of initial determinations made under a drug management program . . . would be subject to the processes set forth at proposed § 423.153(f)." Preamble to the Proposed Rule at 56358. We appreciate this discussion and ask CMS to consider issuing additional guidance around how Part D sponsors should handle coverage determinations in the drug management program context.

- **Recommendation: Issue additional guidance regarding how the coverage determination process interacts with the drug management program for at-risk beneficiaries.**

7. Six Month Lock-In Waiting Period

CMS proposes that "sponsor may not limit an at-risk beneficiary's access to coverage of frequently abused drugs to a selected prescriber(s) until at least 6 months has passed from the date the beneficiary is first identified as a potential at-risk beneficiary" due to concern about the impact on a beneficiary's relationship with their providers and potential provider burden. Proposed Rule at 56354. We agree with CMS that prescriber lock-in should be a tool of last resort and as such are very supportive of CMS including a care management requirement which will help ensure a beneficiary has been appropriately identified for lock-in and provide an opportunity to discuss other approaches that could be less disruptive. That said, we believe that the proposed clinical guideline, care management, and beneficiary protections are sufficient to ensure that a Part D sponsor already views lock-in as a last resort. Further, if after completing all of these steps, a sponsor decides lock-in is still necessary, delaying until six months have passed would place the beneficiary at significant risk.

- **Recommendation: Do not finalize a six-month waiting period; instead allow Part D sponsors to lock-in an at-risk beneficiary after completing the proposed case management, prescriber permission, and beneficiary notification requirements.**

8. Beneficiary Preferences

Section 1860D–4(c)(5)(D) of the Act, as added by CARA, provides that, if an at-risk beneficiary submits preferences for certain pharmacies or prescribers, the Part D sponsor must select those

pharmacies and prescribers based on those preferences. The Proposed Rule further proposes to require that these pharmacies or prescribers be in-network, unless the beneficiary's plan is a stand-alone prescription drug plan (without a provider network) and the beneficiary's preference involves a prescriber. CMS also proposes an exception in a case where the selection would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary.

- **Recommendation: Finalize as proposed.** We appreciate the proposed exception and agree that this is important to ensure beneficiary safety.

Request for Information re: Pass-Through Rebates and Price Concessions

Prescription drug prices are growing faster than any other part of the health care system. Since 2006, drug spending has increased 42% with most of that growth occurring after 2013. Although spending slowed in 2016 compared with the previous two years, CMS continues to project drug spending will continue growing faster than medical spending over the next ten years. The threat of rising prescription drug costs is particularly acute for Medicare beneficiaries. At a time when most Medicare beneficiaries live on a fixed budget and have seen minimal increases in their Social Security income, the growing cost of drugs is forcing seniors to decide between adhering to their doctors' orders and paying for meals or heating bills.

Aetna is very concerned about the rising cost of drugs and, in particular, the astronomical cost of certain new therapies that, while representing a clinical breakthrough, are inaccessible for most beneficiaries due to cost. Aetna supports strong federal and state policies to help reduce high drug costs within the principals of a market based system. To that end, we support policies that directly reduce beneficiary spending such as MedPAC's package of Part D reforms that included eliminating cost-sharing in the catastrophic phase. We understand and agree with CMS' desire to increase transparency in prescription drug prices and the financial struggle faced by the sickest beneficiaries at the point-of-sale; however, we are very concerned the proposals discussed in this RFI if finalized will result in a windfall to manufacturers, higher premiums, and little relief for individual consumers.

We greatly appreciate CMS choosing to issue an RFI rather than propose a specific change in this rule and understand that CMS will undertake additional notice and comment before implementing such a change. This will provide CMS the opportunity to continue to engage plans and others in the stakeholder community to ensure any changes promote greater price transparency and do not have unintended consequences.

Some of our concerns are detailed below.

<u>Manufacturer Gains</u>

While we understand the desire to reduce the growing financial burden of high prescription drug prices, this proposal would serve to increase programmatic costs, ultimately born by taxpayers, and provide manufacturers with a significant windfall. CMS' own analysis estimates that such a proposal would reduce beneficiary costs by only 8 percent, if all rebates are included, while reducing manufacturer liability in the coverage gap by 20 percent and increasing programmatic costs by 6 percent. Even these estimates should raise concern over the size of the benefit that will accrue to pharmaceutical manufacturers; however, we performed an internal analysis based on our own rebate and claims data that showed significantly different results, despite normalizing our overall spend and rebate assumptions to align with those inherent in CMS' analysis.

Our analysis found that the pharmaceutical industry is by far the biggest winner, with coverage gap discount liability being reduced by 50% (versus a modest 4% improvement for the beneficiaries). This translates to more than $60 billion in manufacturer savings over ten years versus $25 billion in beneficiary savings. This does not take in to account any behavioral changes. The reason our analysis differs from CMS' by so much is that CMS assumes that rebates are perfectly substituted with the point-of-sale discount in all phases of the Part D benefit, when in reality rebates are concentrated in the coverage gap and catastrophic benefit phases. When passing rebates through at POS, the financial impact will be determined by the ending phase, not the average phase. As shown in the table below, we estimate that savings to manufacturers are significantly greater than to beneficiaries.

Tables 10b and 10c from Proposed Rule

Analysis Source	**CMS**	**Aetna**	**CMS**	**Aetna**
Percent of Rebate at POS	*100%*	*100%*	*100%*	*100%*
Beneficiary Costs	**-$88.13**	**-$37.32**	**-8%**	**-4%**
Cost-Sharing	-$131.97	-$81.27	-17%	-14%
Premium	$43.84	$43.95	11%	14%
Government Costs	**$127.22**	**$128.41**	**6%**	**5%**
Direct Subsidy	$310.58	$255.90	76%	42%
Reinsurance	-$113.75	-$60.89	-11%	-5%
Low Income Cost-Sharing Subsidy	-$83.42	-$89.39	-14%	-18%
Low Income Premium Subsidy	$13.81	$22.80	12%	8%
Manufacturer Gap Discount	**-$45.48**	**-$91.10**	**-20%**	**-51%**
Total Program Costs	***-$6.39***	***$0.00***		

Drug Pricing Transparency

Pharmaceutical manufacturers and some stakeholder groups have argued that plans and PBMs are obscuring the price concessions offered by reducing premiums rather than passing these discounts through to the point-of-sale. They argue that drug prices would not appear as high if

price concessions were considered. While we acknowledge there is an inherent trade-off between cost-sharing and premiums, we are currently passing these rebates along to our enrollees via one or both of those mechanisms. Reducing the point of sale price, and beneficiary cost-sharing amount, does not shed any light on the true cost of a drug and simply moves money from one bucket to another.

If CMS is interested in true transparency it should consider solutions that increase transparency around manufacturer pricing and profit. For instance, Part D sponsors are subject to very strict MLR requirements that limit the amount of revenue that can go towards profit and operational expenses, risk corridors that return unexpected savings to CMS, and bid reviews. Individual market plans are also subject to rate reviews by the states which require them to justify large annual premium increases. Pharmaceutical manufacturers do not face similar oversight in their pricing and profit decisions. Aetna would support CMS and other Federal efforts to bring true transparency to drug pricing.

Furthermore, CMS acknowledges the need to preserve the confidentiality of price negotiations and is considering a weighted average methodology to calculate the required pass through. This further obscures prices by allowing some manufacturers to be subsidized by others, likely driving all rebates to a lower, standard level for the entire group of drugs.

Potential for Gaming and Adverse Selection

If CMS were to move forward with this proposal, we are very concerned about the potential for gaming by plans and manufacturers. As noted above, calculating the "pass-through rebate" based on a group of drugs reduces the incentives for manufacturers to offer a discount. Manufacturers and plans so inclined may create alternative financial arrangements that are not "rebates" resulting in cost-sharing and programmatic costs both increasing. Plans could also change how they negotiate for rebates, and thus set point-of-sale cost sharing, to avoid certain types of beneficiaries. In some cases, manufacturers may offer large rebates to lower the POS price in order to drive beneficiaries away from more effective alternatives with lower or no rebates. Even if a plan has placed the more expensive, effective alternative on a lower tier, the POS price may still be higher than the less effective option.

In conclusion, while we strongly support CMS' efforts to address the problem of growing prescription drug prices, we are concerned this proposal would not achieve the goal of price transparency while creating a number of avoidable and untended consequences. We would also note that many of these challenges stem from the nature of the Medicare program. Unlike in the commercial market, Medicare beneficiaries often select drug coverage separately from medical coverage, exacerbating the risk of adverse selection and plan shopping based on the price of a single drug. Overtime this could lead to instability in the Part D market, similar to the issues faced by the exchanges..

- **Recommendation: We strongly urge CMS to continue to engage with plans, PBMs, and other stakeholders prior to additional rulemaking and comment on this issue; furthermore, we would encourage CMS to think creatively and develop policies that will result in true drug price transparency and lower beneficiary costs.**