National Alliance on Mental Illness

January 16, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

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

Dear Administrator Verma:

On behalf of the National Alliance on Mental Illness (NAMI), I am pleased to submit the following comments proposed policy and technical changes for Part D for contract year 2019. NAMI is the nation's largest organization representing individuals living with mental illness and their families. Since passage of the Part D program in 2003 and its initial roll-out in 2006, NAMI has taken a strong interest in making sure that the program meets the needs of Medicaid beneficiaries living with mental health conditions.

NAMI supports efforts on the part CMS to undertake continuous review and refinement of both the Part D and Medicare Advantage (MA) programs. NAMI supports efforts by CMS to provide plan sponsors appropriate flexibility in plan operations. However, we also believe that it is important for CMS to balance the goals of plan flexibility with ensuring beneficiary protections. As noted below, the changes contained in this draft rule appear to be seeking solutions to issues that may not be perceived as problems by beneficiaries. Further, some of these proposed solutions could actually jeopardize beneficiary safeguards and protections that are critical to ensuring beneficiary access to vital medications and therapies.

Specifically, NAMI would highlight the following examples in the draft Call Letter and other issues of concern:

- Proposed new limitations for the Part D SEP for Dual-eligible Beneficiaries
- Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes
- Part D Tiering Exceptions
- Request for Information on Rebates at Point of Sale
- Communication of Plan Marketing Materials
- Star Ratings Program

Establishing Limitations for the Part D SEP for Dual-eligible Beneficiaries
CMS is proposing to limit to one Special Enrollment Period (SEP) annually for dual-eligibles and Low-Income Subsidy (LIS) beneficiaries. NAMI understands that that the SEP is not widely-used by the overall LIS population. At the same time, it providers an important avenue to access for those LIS beneficiaries who do elect to use the SEP. NAMI is concerned that this policy becomes even more dangerous when combined with the proposed policy revisions to mid-year formulary changes. Some LIS beneficiaries may

be unable to maintain a treatment regimen to a branded drug when a generic equivalent enters the market as the branded drug may be removed from the formulary.

Under current policy, in this scenario, the LIS beneficiary may switch to a plan still covering the product. This is an important and strong protection for low-income beneficiaries. CMS should consider expanding the limit to 2 to 3 SEPs during a plan year. This would allow CMS to address a problem that, through its own admission, does not exist but could cause access issues for some beneficiaries.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes
CMS here is proposing to allow plans greater flexibility for generic substitutions. Specifically, plans could immediately—any time of year, without 60-day notification—remove a branded product or change cost-sharing to a higher amount when opting to cover a therapeutically equivalent, newly approved generic drug.

The current notification affords plan enrollees time to explore how a transition to a generic drug will affect their treatment regimen. A change in copayment and pill size/shape/color could cause undue stress on beneficiaries and potentially affect adherence. Ample notification, even if it were 30 days, is best for patients.

Part D Tiering Exceptions
CMS is seeking to base eligibility for tiering exceptions on the lowest applicable cost-sharing for the tier containing the preferred alternative for treatment—not simply based on the names of tiers. CMS is also seeking to maintain the current policy that there are no tiering exceptions for products on a specialty tier.

NAMI understands CMS's commitment to finding solutions to provide lower cost-sharing for beneficiaries taking expensive therapies via the tiering exceptions process. We acknowledge the constraints around actuarially equivalence in order to potentially allow lower cost sharing for specialty tier drugs. NAMI would encourage CMS to explore other solutions to reduce the out-of-pocket burden facing these beneficiaries. These could include:

1. performing more stringent discrimination review to ensure that certain classes of drugs are not always placed on specialty tiers; and
2. allowing cost sharing exceptions for specialty tier drugs.

Request for Information on Rebates at Point of Sale
CMS here is seeking stakeholder comments through a request for information (RFI) on the potential to apply some manufacturer rebates at the point of sale for the price of drugs. NAMI applauds the movement to incorporate rebates at the point of sale and allow Medicare beneficiaries to directly benefit from the discounts and rebates provided by manufacturers. CMS should undertake additional guidance on this matter. In NAMI's view, it would be important to consider creative methods for passing pharmacy direct and indirect remuneration (DIR) to point-of-sale. NAMI looks forward to additional guidance on this move to the extent pharmacy DIR at point-of-sale ultimately saves money for beneficiaries.

PDP Meaningful Differences Policy
CMS is proposing to eliminate the meaningful differences requirement between two enhanced prescription drug plans (PDPs) offered by a PDP sponsor in one region. NAMI supports the existing meaningful differences policy to help beneficiaries distinguish between different stand-alone PDPs offered by the same Part D plan sponsor in a region. While we are not necessarily opposed to removing

the meaningful difference between two enhanced PDPs, we strongly encourage CMS to look for innovative ways to communicate plan options so that beneficiaries can find the plan that best meets their individual needs.

Communication of Plan Marketing Materials
CMS proposes that MA and Part D plans provide benefit package information to prospective enrollees at the start of the Annual Election Period (AEP), not 15 days before, as currently required. Further, CMS is proposing to require plans to mail hard copies of the evidence of coverage, summary of benefits, and provider network information only upon request.

NAMI is concerned that this proposal would remove an important step in communicating benefit design, formulary, and provider network changes in advance of the upcoming plan year. Instead, NAMI would encourage CMS to maintain the policy that plan sponsors must provide plan benefit package information 15 days prior to the AEP and that hard copies should be provided.

Star Ratings Program
CMS here is proposing to assign a contract score based on the enrollment-weighted average of the measure scores of both the surviving and consumed contract(s) in order to reflect the performance of all contracts associated with a consolidation. Further, this proposal seeks to explore the feasibility of assigning an overall score at the plan level rather than the contract level (as is currently done.) CMS is seeking comments on maintaining the high-performing or low-performing icons displayed on the Plan Finder tool.

NAMI supports CMS' effort to better reflect plan performance when a contract consolidation occurs as this will offer a more accurate view of the new contract's performance on important quality measures. Similarly, NAMI supports CMS' exploring a process that would assign scores at the plan level rather than the contract level as performance may vary significantly across a contract's plans. Most importantly, NAMI recommends that CMS maintain the high and low-performing icon on the Plan Finder tool so that prospective beneficiaries shopping for plan coverage will know which plans have received high or low-quality measures.

Conclusion
Thank you for the opportunity to offer comments on the 2019 Policy and Technical Changes to the Part D and MA Prescription Drug Benefit Programs.

Sincerely,

Angela Kimball
National Director, Advocacy & Public Policy