Medicare Payment Advisory Commission (MedPAC) 425 Eye Street NW, Suite 701 Washington, DC 20001

Dear Commissioners:

The undersigned organizations write to urge the Medicare Payment Advisory Commission (MedPAC) to conduct a comprehensive, in-depth analysis of the Medicare Part D exceptions and appeals process and to issue recommendations on how to improve the appeals system. Our organizations share a commitment to advancing the health and economic security of people with Medicare and their families.

We continue to observe that older adults and people with disabilities struggle to navigate the multi-step Part D appeals process, threatening their access to needed medications. Given these experiences, we support a careful review of Part D exceptions and appeals by MedPAC, specifically to identify opportunities to ease challenges faced by beneficiaries and their prescribers when medically-necessary prescription drugs are denied or when the cost sharing for such medicines becomes burdensome. A robust, accessible and functional appeals process is essential to a well-functioning program and is an absolute prerequisite to proposed adjustments to the Part D program that may impede access to needed prescriptions or alter formularies.

Upon review of the available qualitative and quantitative data on Part D appeals, we support MedPAC's March 2014 determination that, "...these findings suggest a need for increased transparency and streamlining of the processes involved so that beneficiaries and physicians are not discouraged from seeking exceptions for medications." Subsequently, in July 2014, the Centers for Medicare & Medicaid Services (CMS) released planlevel data on pharmacy transactions, coverage determinations, and redeterminations by Part D plans. Given the Commission's initial conclusions, we believe the release of this data warrants additional analysis by MedPAC.²

Also, since MedPAC released its first review, CMS made available its 2013 audit of select Part D and Medicare Advantage (MA) plan sponsors. The results of this audit are cause for alarm. For instance, CMS determined that, among audited sponsors, 89% issued denial letters to beneficiaries that either failed to include an adequate rationale or contained incorrect information, 78% failed to demonstrate sufficient outreach to obtain additional information necessary to make an appropriate clinical decision, and 56% made inappropriate denials when processing coverage determinations. At the same time, 61% were shown to apply unapproved quantity limits and 50% were shown to apply unapproved utilization management practices.³

Since the beginning of 2014, CMS has imposed sanctions, most often civil monetary penalties, on 30 MA and Part D sponsors. Of these, 27 involved failures to comply with requirements related to Part D coverage determinations, appeals, and grievances. In nearly all cases, CMS notes that noncompliance "...resulted in enrollees experiencing

¹ MedPAC, "Report to the Congress: Medicare Payment Policy" (March 2014; pgs. 368-369), available at: http://www.medpac.gov/documents/reports/mar14 entirereport.pdf?sfvrsn=0

² CMS, "Part C and Part D Data Validation," (July 2014), available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html

³ CMS, "Common Conditions, Improvement Strategies, and Best Practices based on 2013 Program Audit Reviews," (Memo from G. Mulcahy to All Medicare Advantage Organizations and Prescription Drug Plans; August 27, 2014), available at: http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html

inappropriate delays or denials in receiving covered benefits and increased out-of-pocket costs." Most often these sanctions resulted directly from CMS audits. Unfortunately, as CMS acknowledged in its proposed 2015 contract rule, the agency is limited in its capacity to audit sponsors, reviewing only 30 of 300 sponsors (10%) annually. Given this, it is difficult to know the full extent of these problems. Nevertheless, we believe the available information on audits and sanctions present reasonable cause for MedPAC to further examine the appeals process.

CMS has also made available 2012 and 2013 data on Part D reconsiderations—the third formal level of appeal and the first level of review conducted by an Independent Review Entity (IRE). Among reconsiderations, CMS found that an IRE reversed 42% of plan-level decisions in 2012 and 32% in 2013.⁶ At first glance, this downward trend seems to suggest a favorable change. Yet, the reasons behind this development merit additional scrutiny, specifically to evaluate whether this reflects improved plan-level accuracy, decreased IRE scrutiny, or both. Also notably, IRE reversal rates for cases involving utilization management controls remain unreasonably high—57% in 2012 and 47% in 2013.⁷

Furthermore, our experience suggests that those specific cases not captured in this data set, where the appeal is dismissed or remanded, tend to be highly representative of instances where a beneficiary and/or a prescriber erroneously mismanage an exceptions request. We are concerned that these cases where technical deficiencies result in a plan's determination being upheld without review cause beneficiaries to go without needed medications. We encourage MedPAC to examine whether the procedural requirements for appeals are overly onerous or could be made more adaptable to beneficiary needs. Considered all together, we believe recently released data on audits, sanctions, and reconsiderations suggest significant room for improvement in the operation of Part D exceptions and appeals.

In closing, we believe that MedPAC is well-suited to evaluate the Part D appeals system and to suggest specific recommendations to improve the Part D exceptions and appeals process. We ask you to revisit this issue and to release your findings in an upcoming report to Congress. We welcome the opportunity to discuss our request with you in greater detail. Thank you.

Sincerely,

AARP

American Association on Health and Disability Center for Medicare Advocacy, Inc. Epilepsy Foundation Families USA Lupus Foundation of America

⁴ Determined through review and analysis of individual sanction letters sent to MA and Part D sponsors as of September 24, 2014; see: CMS, "Part C and Part D Enforcement Actions," (2008 – 2014), available at: http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Enforcement-Actions-.html#

⁵ "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule" 79 Fed. Reg. 7 (Jan. 10, 2014) p. 1927 (to be codified at 42 CFR Parts 409, 417, 422, et al.)

⁶ CMS, "Fact Sheet: Part D Reconsideration Appeals Data – 2013" (2013); CMS, "Fact Sheet: Part D Reconsideration Appeals Data – 2012" (2012), both available at: http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Reconsiderations.html; These data points exclude cases that were dismissed, withdrawn or remanded as well as cases involving non-Part D drugs. In 2013, IRE reversals rates for non-Part D drugs amounted to 24%. Coverage determinations for non-Part D drugs are based on bright-line coverage rules. As such, we would expect plan-level coverage determinations to be fairly straightforward, lending to an IRE reversal rate nearer to zero than is currently reflected in the data. Appeals cases involving non-Part D drugs also warrant additional analysis by MedPAC.

⁷ Ibid. Excludes cases dismissed, withdrawn or remanded.

Medicare Rights Center

National Alliance on Mental Illness

National Association of Nutrition and Aging Services Programs (NANASP)

National Association of Professional Geriatric Care Managers

National Association of Social Workers (NASW)

National Committee to Preserve Social Security and Medicare

National Community Pharmacists Association

National Council on Aging

National Organization for Rare Disorders (NORD)

National Psoriasis Foundation

National Senior Citizens Law Center

OWL-The Voice of Women 40+

Parkinson's Action Network

Research!America

RetireSafe

The AIDS Institute

The Arc of the United States