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March 17, 2016

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

Dear Commissioners:

On behalf of the Medicare Rights Center (Medicare Rights), I am writing to comment on select recommendations presented by Chairman Crosson to the Medicare Payment Advisory Commission (MedPAC) on March 3, 2016. Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Our organization provides services and resources to over two million beneficiaries, family caregivers, and professionals annually.

Placing a hard cap on beneficiary cost sharing in Part D (Recommendation #1): Among other changes to Part D reinsurance, the Chairman recommends eliminating enrollee cost sharing above the out-of-pocket threshold, essentially replacing catastrophic coinsurance with a hard cap on out-of-pocket spending. We applaud this proposal, and we encourage the Commissioners to support this recommendation.¹

Under current law, beneficiaries not enrolled in the Low-Income Subsidy (LIS) who reach the Part D catastrophic phase are responsible for a 5 percent coinsurance on all prescription drugs. While this coinsurance appears minimal, a recent analysis by the Kaiser Family Foundation finds that the high cost of specialty medications can present a significant burden in the catastrophic phase. The report demonstrates that spending on select specialty medications during the catastrophic phase, such as for rheumatoid arthritis and cancer, can range from 34 to 76 percent of a non-LIS beneficiary's total costs for a single year.²

¹ Medicare Payment Advisory Commission (MedPAC), "Public Meeting Transcript," (March 2016; pg. 135-136), available at: http://www.medpac.gov/documents/0316_meeting_transcript.pdf?sfvrsn=0

² Hoadley, J., Cubanski, J., and T. Neuman, "It Pays to Shop: Variation in Out-of-Pocket Costs for Medicare Part D Enrollees in 2016," (Kaiser Family Foundation: December 2015), available at: <http://kff.org/report-section/it-pays-to-shop-variation-in-out-of-pocket-costs-for-medicare-part-d-enrollees-in-2016-findings/>

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These findings are reflective of challenges expressed by callers to our national helpline. We observe that beneficiaries living on low, fixed incomes—though not low enough to qualify for LIS—are going without needed medications due to high cost sharing. Research consistently demonstrates that costly copayments, coinsurance, and deductibles lead people to forgo medically necessary care.³ A hard cap on Part D cost sharing would shield older adults and people with disabilities from unaffordable cost sharing on needed prescription drugs, likely leading to improved adherence and health outcomes.

Eliminating generic copayments for people with the Low-Income Subsidy (LIS) (Recommendation #2):

The Chairman recommends slightly revising a 2012 MedPAC recommendation to alter LIS copayments.⁴ We continue to strongly support the elimination of cost sharing for lower-cost medications for LIS enrollees, including generic prescription drugs, preferred multi-source medications, and biosimilars. Yet, we remain opposed to the Commission’s 2012 proposal to increase cost sharing for brand name medications.⁵

MedPAC acknowledges that the disproportionate use of brand name medications among low-income beneficiaries is partly driven by prescriber behavior.⁶ Research on cost sharing and patient behavior demonstrates that it is health care providers who drive service utilization—not patients.⁷ Indeed, callers to our national helpline are often reluctant to question their provider’s choices. Given this, we are concerned about access to generic medications among beneficiaries with providers who do not readily prescribe those treatments and the adverse consequences that may result from higher cost sharing for brand name prescription drugs.

Further, several studies confirm that low-income populations remain skeptical of generic medications, fearing that generic alternatives are lower quality and more likely to cause side effects compared to brand name drugs. One 2011 study found that low-income participants in a rural Alabama community outreach program chose to go without refills of their prescribed brand name medications because of the cost and did not substitute available generic options.⁸

Educational initiatives are needed to explain the merits of generic prescription drugs—both for health care providers and for Medicare beneficiaries, particularly among LIS enrollees. We believe these educational efforts should be pursued before imposing additional cost burdens on this vulnerable population, and we encourage MedPAC to address these issues as the Commissioners revisit the prior recommendations on LIS copayments.

Permitting additional formulary flexibilities for Part D plans (Recommendation #3): The Chairman recommends a collection of proposals to enhance formulary flexibility among Part D plan sponsors, including: scaling back the protected classes (removing antidepressants and immunosuppressants); streamlining the process

³ Swartz, K. "Cost-Sharing: Effects on Spending and Outcomes" Robert Wood Johnson Foundation Research Synthesis Report No. 20 (December 2010)

⁴ Medicare Payment Advisory Commission (MedPAC), "Public Meeting Transcript," (March 2016; pg. 137-139), available at: http://www.medpac.gov/documents/0316_meeting_transcript.pdf?sfvrsn=0

⁵ Letter to MedPAC from the Medicare Rights Center (September 20, 2013), available at: <http://www.medicarerights.org/pdf/092013-part-d-appeals-medpac.pdf>; Leadership Council of Aging Organizations (LCAO), "Altering Extra Help Copayments," (January 2014), available at: <http://www.lcao.org/issue-brief-altering-extra-help-copayments/>

⁶ Medicare Payment Advisory Commission (MedPAC), "Report to the Congress: Medicare Payment Policy: Chapter 13" (March 2012), available at: <http://www.medpac.gov/documents/reports/march-2012-report-to-the-congress-medicare-payment-policy.pdf>

⁷ For a findings on the utility of cost sharing for patients already in the health care system, refer to: RAND, "The Health Insurance Experiment: A Classic RAND Study Speaks to the Current Health Care Reform Debate" (January 2006), available at: http://www.rand.org/pubs/research_briefs/RB9174.html

⁸ Thomas, K., "Why the Bad Rap on Generic Drugs?" The New York Times (October 5, 2013)

for mid-year formulary changes; establishing more rigorous requirements for physician statements that accompany exceptions requests; and permitting plans to use additional tools to manage specialty medications.⁹

In the absence of needed improvements to the Part D appeals process, we are deeply concerned that the proposed formulary flexibilities, specifically the changes to the protected classes, could limit beneficiary access to needed medications. Should MedPAC approve Recommendation #3, we urge the Commissioners to condition the recommendation on improvements to the Part D coverage determination and appeals processes. In particular, we strongly encourage MedPAC to endorse proposals to improve beneficiary notification at the point of sale and minimize steps in the appeals process for Part D enrollees.

The erosion of existing consumer protections and enhancement of formulary flexibility for Part D sponsors should be coupled with improvements to the exceptions and appeals process, in addition to formulary review and transparency as well as transition fills. On this subject, we encourage the Commissioners to review Medicare Rights' testimony before the U.S. House Energy & Commerce Committee on a prior proposal by the Centers for Medicare & Medicaid Services (CMS) to scale back the protected classes (see Attachment One).¹⁰

We appreciate MedPAC's interest in allowing formulary designs among Part D plans that permit sponsors to negotiate better prices on prescription drugs. Nevertheless, we are increasingly concerned by the complexity of Part D formularies, currently including up to five tiers with blended brand and generic medications, varying use of coinsurance and copayments, and the proliferation of utilization management tools across tiers. This complexity makes the Part D benefit increasingly difficult for beneficiaries to comprehend and leads to persistent challenges as people seek to compare and contrast plan options.

Additionally, as noted in the Chairman's presentation, some of the recommended flexibilities will create the risk that more and more beneficiaries will need to request exceptions, redeterminations, and appeals.¹¹ In its March 2014 report to Congress, MedPAC acknowledged persistent shortcomings with the Part D appeals process. Upon review of the available qualitative and quantitative research on Part D appeals, the Commission concluded, "...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."¹²

Following this report, 20+ leading consumer advocates urged MedPAC to further investigate Part D appeals, referencing systemic failures by plan sponsors to manage denials, coverage determinations, and appeals, as documented through CMS' audit results and enforcement actions (see Attachment Two). Year after year, beneficiary questions concerning prescription drug denials present as the top trend on Medicare Rights' national helpline.¹³ To date, we continue to observe that Part D enrollees struggle to navigate an overly onerous appeals

⁹ Medicare Payment Advisory Commission (MedPAC), "Public Meeting Transcript," (March 2016; pg. 139-145), available at: http://www.medpac.gov/documents/0316_meeting_transcript.pdf?sfvrsn=0

¹⁰ Baker, J., "Testimony Prepared for the U.S. Energy & Commerce Committee," (February 2014), available at: <http://docs.house.gov/meetings/IF/IF14/20140226/101788/HHRG-113-IF14-Wstate-BakerJ-20140226.pdf>

¹¹ Medicare Payment Advisory Commission (MedPAC), "Public Meeting Transcript," (March 2016; pg. 144), available at: http://www.medpac.gov/documents/0316_meeting_transcript.pdf?sfvrsn=0

¹² Medicare Payment Advisory Commission (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

¹³ Sutton, C., Bennett, R., Sanders, S., and F. Riccardi, "Medicare Trends and Recommendations: An Analysis of 2012 Call Data from the Medicare Rights Center's National Helpline," (2014), available at: <https://www.medicarerights.org/2012-medicare-trends>; Morales, S., Bennett, R., and Sanders, S., "Medicare Trends and Recommendations: An Analysis of 2013 Call Data from the Medicare Rights Center's National Helpline," (2015), available at: <https://www.medicarerights.org/2013-medicare-trends>; Morales, S., Schwarz, C., and

process—resulting in delays in access to needed prescription drugs, abandonment of prescribed medications, reduced adherence to treatment protocols, and higher health care costs.

The Chairman’s March 2016 presentation summarizes concerns from beneficiaries, from providers, from health plans, and from CMS with the Part D appeals process. Yet, the Chairman includes only one recommendation to improve the Part D appeals process within Recommendation #3—to require prescribers to provide supporting statements with more clinical rigor when applying for exceptions. On its own, we suspect this recommendation could make the Part D appeals process all the more difficult for beneficiaries to navigate.

To be successful, a supporting statement from a provider must accompany an exception request. Based on our experience, provider willingness to participate in the appeals process varies, with some more willing than others to expend the time and resources necessary to supply these statements. While we agree that clinical information should be a necessary condition for any exception request, we are concerned that the proposed requirements will act as a deterrent for health care providers who might otherwise assist with appeals.

Additionally, we note that the Chairman’s recommendations fail to incorporate needed improvements to the Part D appeals process that are ultimately intended to benefit consumers. To ensure that Part D enrollees are able to successfully navigate the appeals process, we continue to advocate for improved information at the point of sale and a streamlined appeals process.

We strongly believe that access to information about the reason for a plan denial—provided at the pharmacy counter—will both eliminate significant beneficiary confusion and limit delays in accessing needed medications. Armed with information about why a prescription drug was refused at the pharmacy counter, Part D enrollees and their providers will be better equipped to determine the best course of action for the beneficiary’s health. Along these same lines, we strongly support allowing the pharmacy counter refusal to serve as the coverage determination. This proposal serves the dual purpose of removing a burdensome step for beneficiaries and their prescribers, first, by explicitly stating why the drug is not covered and, second, by expediting the appeals process for those who need it.

We note that the aforementioned recommendations represent long-term solutions, as pursuing either of these proposals will require the National Council for Prescription Drug Programs (NCPDP) to update electronic transaction standards under the Health Insurance Portability and Accountability Act (HIPAA). Nevertheless, we encourage MedPAC to recognize these options as viable and worthwhile pursuits.

At the same time, we continue to support efforts underway at CMS to explore opportunities to help beneficiaries secure access to needed medications absent coverage determination requests and appeals. We also remain strongly supportive of commitments made by CMS in 2016 to strengthen beneficiary denial notices and to establish a data tracking system to monitor each stage of the Part D appeals process. We encourage MedPAC to express support for these solutions as well, and we invite the Commissioners to review comments submitted by Medicare Rights to CMS on these initiatives in the 2017 Advance Call Letter (see Attachment Three).

In closing, we thank Chairman Crosson and the Commissioners for their thoughtful deliberation on these important issues. We strongly support the Chairman’s recommendations to place a hard cap on Part D cost sharing and to eliminate cost sharing for generic and biosimilar medications for LIS enrollees. Yet, we are

F. Riccardi, “Medicare Trends and Recommendations: An Analysis of 2014 Call Data from the Medicare Rights Center’s National Helpline,” (2016), available at: <https://www.medicarerights.org/2014-medicare-trends>

deeply concerned about the recommendations to grant additional formulary flexibilities among Part D plans, especially in the absence of beneficiary-friendly improvements to the Part D exceptions and appeals process.

If you have questions, please contact Stacy Sanders, Federal Policy Director, at ssanders@medicarerights.org or 202-637-0961. Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Baker". The signature is fluid and cursive, with a large loop on the "J" and a long tail on the "B".

Joe Baker
President
Medicare Rights Center

Attachment One: Excerpt from February 2014 Testimony to U.S. House Energy & Commerce Committee

Testimony of Joe Baker
President, Medicare Rights Center

Prepared for the
United States House of Representatives
Energy & Commerce Committee, Subcommittee on Health

February 26, 2014

Scaling back the protected drug classes. In Part III, A, Section 14, CMS proposes replacing the requirement that all Part D plans cover all available medications in six designated protected classes with a two-step test to determine which categories of medications are of sufficient clinical concern to merit continued protected access. Upon application of this test, CMS determines that antidepressants, immunosuppressants, and antipsychotics no longer meet the requirement for enhanced protections.

CMS' proposed rule relies on the appropriate functioning of beneficiary protections, including formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the coverage determination and appeals processes, to justify easing robust formulary requirements for protected drug classes. Medicare Rights' experience serving Medicare beneficiaries suggests, however, that these protections are insufficient. In particular, we have continuously suggested that CMS critically examine and streamline the Part D appeals process, and we believe increased transparency about how well the appeals system operates is needed.

Given the shortcomings of the appeals process and other beneficiary protections, namely formulary transparency and transition supplies, we cannot support the proposed changes to the protected classes at this time. Our specific concerns include the following:

The Part D appeals process needs significant repair. In 2012, over one third (33%) of calls to the Medicare Rights helpline concerned denials of coverage and appeals, making up the largest proportion of inquiries to the helpline. Recent findings by MedPAC confirm that many beneficiaries are unaware of their right to appeal and do not know how to go about initiating the appeals process.¹⁴ We observe the following trends with respect to Part D appeals:

First, we find that people with Medicare are not provided individualized information or adequate education when refused a medication at the pharmacy counter. As such, beneficiaries must embark on a tedious, fact-finding search to learn the reason for the refusal and to determine the best path forward. Pharmacists may have limited or incomplete information and can only direct a beneficiary to call the drug plan for the denial reason. Beneficiaries often face long call wait times and inconsistent customer service when trying to obtain this information.

¹⁴ Presentation by Sokolovsky, L., Suzuki, S. and L. Metayer, "Part D exceptions and appeals" (September 2013), available at: http://www.medpac.gov/transcripts/part_d_exceptions_&_appeals.pdf; CMS, "Fact Sheets: Part D Reconsideration Appeals Data, Part D Fact Sheets CY 2011" (2011), available at: <http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Reconsiderations.html>

Next, we observe that the multi-step Part D exceptions and appeals process proves onerous and time-consuming for beneficiaries, pharmacists, and prescribing physicians. Although denied coverage at the pharmacy counter, this refusal does not constitute a formal denial by the plan, which would entitle the person to an appeal. Instead, with the support of the prescribing physician, a beneficiary must formally make an exception request. Only upon receipt of a written denial in response to this request, known as the coverage determination, is the beneficiary permitted to request a formal appeal, termed a redetermination.

While this multi-step process is described clearly here, it is important to note that this course of action may involve multiple phone calls and long wait times, often up to many days, for beneficiaries seeking access to a needed medication. A person must correspond with both their plan and their prescribing doctor on multiple occasions to see the coverage determination and redetermination phases through.

The current system is constructed in such a way that Part D drug plans are effectively granted three chances to make a correct determination about covering a prescribed medication: at the pharmacy counter, in the coverage determination, and in the redetermination. It is worth noting that this three-step process is distinct from Medicare Advantage (MA), Original Medicare, and Medicaid appeal frameworks. In these health programs, a beneficiary receives a notice of non-coverage after a service is received or prior to the service because it is not authorized. Unlike Part D, beneficiaries are not expected to formally request notice of non-payment after refusal of a service.

To date, there is no data or analyses available to the public or reflected in the proposed rule to suggest how often improper denials are corrected at the plan level. Further, what appeals data exists is not reassuring. CMS's 2012 audit suggests that Part D plans struggle most with managing coverage determinations, appeals, and grievances. Additionally, 2011 data released by the agency finds that over half (54%) of plan-level denials are overturned by the Independent Review Entity (IRE), which conducts the first post-plan level—and truly independent—review.

This alarming rate of reversals by the IRE, coupled with CMS' own audit data on plans, raises serious questions about how well the redetermination and appeals process is working, and demands greater transparency. We urge members of Congress to request that CMS make plan-level appeals data accessible in easy-to-comprehend formats so that targets for improvement can be identified.

More importantly, we strongly believe that the Part D appeals process must be streamlined and tested ahead of any changes that would relax the protected classes. A straightforward approach to improving the appeals process would combine a point-of-sale refusal with a formal request for a coverage determination, as suggested in a recent letter to CMS signed by members of the Senate Finance Committee.¹⁵ Allowing the pharmacy counter refusal to serve as the coverage determination serves the dual purpose of removing a burdensome step for beneficiaries and their doctors while also expediting the appeals process for those who need it.

Formulary review and transparency need improvement. We believe that CMS sets an unreasonably low bar for evaluating beneficiaries' formulary needs. In the proposed rule, CMS writes, "...with our more than 7 years of experience with the Part D program, we are not aware of any Part D drug that is not included on at least one Part D formulary. Thus, beneficiaries who review plan formularies [on Plan Finder] can select plans that cover all of their current medications."¹⁶ This statement is highly problematic as justification for reducing formulary protections for two key reasons:

¹⁵ Thomas, K. and R. Pear, (February 21, 2014) "Plans to Limit Some Drugs in Medicare is Criticized," *New York Times*, available at: http://www.nytimes.com/2014/02/22/business/plan-to-alter-medicare-drug-coverage-draws-strong-opposition.html?_r=0

¹⁶ Proposed rule at 1939

First, it is inconsistent with Medicare Rights' experience helping tens of thousands of beneficiaries review their coverage options. While it may be accurate that there is no Part D drug that is not on at least one formulary, the same plan options are not available in all areas of the country, and beneficiaries must select a Part D plan within their geographic area. Furthermore, many beneficiaries, particularly those with complicated health status, take more than one prescription. The fact that drug A is on the formulary of Plan X and drug B is on the formulary of Plan Y is not sufficient for a person who must take both A and B.

Second, this statement ignores the well-documented shortcomings of the Plan Finder tool. As a recent GAO report found, despite CMS oversight and improvements, beneficiaries still encounter inaccurate and out-of-date information on Plan Finder.¹⁷ On an annual basis, Medicare Rights provides detailed recommendations to CMS about needed improvements to Plan Finder, drawing directly from our experience serving 2,500+ beneficiaries during the open enrollment period. Among our recommendations are to add appropriate MA plan content, most notably information concerning provider networks, ensure the clarity and accuracy of mail order information, improve the accuracy of cost sharing data, and more.¹⁸

We believe that CMS should take steps to improve both beneficiary education and Plan Finder before restricting access to some of the most urgently needed medications. Members of Congress should explore how to make the appropriate resources available to CMS to support making the Plan Finder a more robust and user-friendly tool.

Access to transition fills is inconsistent. Transition fills, coverage for one month for a continuing treatment when there has been a plan or formulary change, are an essential protection that we find many beneficiaries do not receive. In 2013, CMS continued a transition-fill monitoring program in response to widespread failure to provide appropriate transition refills to those entitled to them.¹⁹ CMS has attempted to address failures to properly effectuate transition fill by drug plans in the past, without improvement. These systematic failures underscore the need for on-formulary access to a wide range of medications for certain classes of drugs.

Uninterrupted treatment on a specific medication is particularly essential for antidepressants, antipsychotics, and immunosuppressants, the very same drugs for which CMS suggests protected status should be relaxed. We applaud CMS for implementing the transition-fill monitoring program. Yet, we believe that CMS should wait for the full results, and publish those results, before relying on transition fills as an appropriate fail-safe for securing access to these essential medications.

In addition to these known shortcomings, transition fills are only available to a narrow band of beneficiaries. Individuals previously stabilized on a particular antidepressant, for example, but who are untreated for a period of time are not eligible for a transition fill if they must return to treatment. In these cases, a beneficiary's physician likely knows which specific medication is best suited to the person's health needs. In the absence of broad formulary protections, these beneficiaries may not be able to access the particular medicine essential to their health. In short, transition fills will not adequately protect these beneficiaries from diminished access to needed prescriptions if the protected classes are not preserved.

¹⁷ GAO, "CMS Has Implemented Processes to Oversee Plan Finder Pricing Accuracy and Improve Website Usability," (January 2014), available at: <http://www.gao.gov/products/GAO-14-143>

¹⁸ Medicare Rights Center, "MEMO to the Centers for Medicare & Medicaid Services re: Plan Finder Observations during Fall Open Enrollment: October 15, 2012 – December 17, 2012," (March 2013)

¹⁹ CMS, "MEMO re: Contract Year 2013 Part D Transition Monitoring Program Analysis," (December 2012), available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/ContractYear2013PartDTransitionMonitoringProgramAnalysis.pdf>

Targeted interventions are needed for overprescribing in long-term care settings. CMS presents no evidence to suggest that open access to protected classes of medications on Part D formularies results in widespread overutilization, with the exception of inappropriate prescribing of antipsychotic medications in nursing home settings. Like CMS, Medicare Rights is deeply concerned about this trend, and we encourage both CMS and members of Congress to explore targeted interventions in these settings to limit these egregious prescribing practices.

As such, we support CMS' proposed policy to target providers who prescribe antipsychotics for patients with dementia in direct violation of the drug's Food and Drug Administration (FDA) approved black box warning. Additionally, we urge CMS to explore partnerships with state boards that oversee prescriber and nursing facility practices, or to develop targeted, narrow exceptions to the protected class status to allow prior authorization requirements in certain prescription settings. These solutions would target abusive prescribing behaviors in specific settings, rather than jeopardize access for beneficiaries living in community settings who must access these medications.

Attachment Two: October 2014 Letter to MedPAC Commissioners

October 10, 2014

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."²⁰ Subsequently, in July 2014, the Centers for Medicare & Medicaid Services (CMS) released plan-level 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.²¹

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

²⁰ 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

²¹ CMS, "Part C and Part D Data Validation," (July 2014), available at: <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDDataValidation.html>

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.²²

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 inappropriate delays or denials in receiving covered benefits and increased out-of-pocket costs.”²³ 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.²⁴ 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 2013.²⁵ 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 2013.²⁶

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

²² 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>

²³ 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-Compliance-and-Audits/Part-C-and-Part-D-Enforcement-Actions-.html#>

²⁴ “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.)

²⁵ 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.

²⁶ *Ibid.* Excludes cases dismissed, withdrawn or remanded.

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

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

Attachment Three: Excerpt from Comments on the 2017 Advance Call Letter

March 4, 2016

VIA ELECTRONIC SUBMISSION

AdvanceNotice2017@cms.hhs.gov

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter

Point of Sale Pilot:

Ongoing Challenges with Part D Appeals and CMS Commitments Identified in 2016: We appreciate CMS' continued focus on improving the beneficiary experience with Part D denials and appeals, especially as we continue to observe that people with Medicare struggle to navigate an overly onerous Part D appeals process—resulting in delays in access to needed prescription drugs, abandonment of prescribed medications, reduced adherence to treatment protocols, and higher than appropriate out-of-pocket health care costs for older adults, people with disabilities, and their families.²⁷

Medicare Rights fields up to 17,000 questions on its national helpline each year, and annual analyses of common trends among our callers continues to reveal that challenges with Part D denials and appeals remain a top concern.²⁸ In 2014, more than one in three calls to the Medicare Rights helpline concerned denials and appeals, most often from Part D and MA enrollees, and 38 percent of clients who inquired about their inability to access a prescription drug were unsure why they were unable to fill a prescription at the pharmacy or why they were denied by their health plan.²⁹

Our experience, coupled with CMS' reporting on poor audit results and related sanctions,³⁰ informed our strong support for several initiatives identified in the 2016 Announcement and Final Call Letter, including:

- Improving Part C and Part D denial notices;

²⁷ Letter to MedPAC from 30+ consumer advocates and health care providers (October 10, 2014), available at:

<http://www.medicarerights.org/pdf/101014-medpac-part-d-appeals.pdf>; Letter to MedPAC from the Medicare Rights Center (September 20, 2013), available at: <http://www.medicarerights.org/pdf/092013-part-d-appeals-medpac.pdf>

²⁸ See: Sutton, C., Bennett, R., Sanders, S., and F. Riccardi, "Medicare Trends and Recommendations: An Analysis of 2012 Call Data from the Medicare Rights Center's National Helpline," (2014), available at: <https://www.medicarerights.org/2012-medicare-trends>; Morales, S., Bennett, R., and Sanders, S., "Medicare Trends and Recommendations: An Analysis of 2013 Call Data from the Medicare Rights Center's National Helpline," (2015), available at: <https://www.medicarerights.org/2013-medicare-trends>; Morales, S., Schwarz, C., and F. Riccardi, "Medicare Trends and Recommendations: An Analysis of 2014 Call Data from the Medicare Rights Center's National Helpline," (2016), available at: <https://www.medicarerights.org/2014-medicare-trends>

²⁹ Morales, S., Schwarz, C., and F. Riccardi, "Medicare Trends and Recommendations: An Analysis of 2014 Call Data from the Medicare Rights Center's National Helpline," (2016), available at: <https://www.medicarerights.org/2014-medicare-trends>

³⁰ Our experience is matched by CMS' own audit findings and high incidences of related sanctions, which suggest significant room for improvement by Part D plans with respect to coverage determinations and appeals. Refer to our 2016 call letter comments for a detailed summary of troublesome findings related to plan audits as well as high rates of unfavorable plan decisions overturned by the IRE, available at: <http://www.medicarerights.org/wp-content/uploads/2015/03/medicare-rights-advance-2016-call-letter-Comments.pdf>. We note that CMS' most recent summary report determined that Part D plans had shown improvement in overall audit scores for 2014, including notable improvements in coverage determinations, appeals, and grievances. While it is encouraging that general improvements have been documented, no specifics have been publicly released.

- Clarifying guidance on required plan outreach to prescribers;
- Establishing a data tracking system for each stage of the appeals process, for use by 2018;
- Beginning work with the National Council for Prescription Drug Programs (NCPDP) to “develop and implement strategies for enhanced messaging” at the pharmacy counter; and
- Carrying out the Point of Sale (POS) Pilot (as referenced in the 2017 Advance Notice and Call Letter).³¹

We are deeply disappointed that the 2017 Advance Notice and Call Letter provides an update on only one of these initiatives, and we urge CMS to provide a status report on the agency’s progress on these other critically important commitments. We strongly encourage CMS to follow through on these initiatives, and to adequately engage multiple, diverse stakeholders (including, but not limited to, Part D plan enrollees, Medicare beneficiary advocates, pharmacists, plan sponsors, pharmacy benefit managers, and pharmaceutical manufacturers) on these activities, ideally through the establishment of a multi-stakeholder workgroup.

We continue to believe that Medicare beneficiaries refused access to a medication at the pharmacy counter would best be served through reforms to the Part D appeals process, both by making additional information available at the POS and by eliminating needless steps in the appeals process. Part D enrollees experience this “turning away” at the POS as a denial, and many struggle to understand why a formal request for coverage must be made to the plan with the support of the prescribing physician.

As such, we strongly believe that access to information about the reason for a plan denial—provided at the pharmacy counter—will both eliminate significant beneficiary confusion and limit delays in accessing needed medications. Armed with information about why a prescription drug was refused at the POS, Part D enrollees and their providers will be better equipped to determine the best course of action for the beneficiary’s health.

Along these same lines, we strongly support allowing the pharmacy counter refusal to serve as the coverage determination. This proposal serves the dual purpose of removing a burdensome step for beneficiaries and their prescribers, first by explicitly stating why the drug is not covered and, second, by expediting the appeals process for those who need it.

We understand that the aforementioned recommendations represent long-term solutions, as pursuing either of these options will involve working in collaboration with the NCPDP to update electronic transaction standards under the Health Insurance Portability and Accountability Act (HIPAA) and likely require a multi-year time commitment. As such, we ask CMS to report on the agency’s work with the NCPDP to consider enhanced communications at the POS, as referenced in the 2016 Announcement and Final Call Letter.³²

Reaction to the POS Pilot: We are grateful for CMS’ reporting on the Part D POS pilot, and we continue to support the agency’s desire to conduct additional research on how to help beneficiaries secure coverage for needed medications after being turned away at the POS. We recognize that not all Part D enrollees refused at the POS will need to request a coverage determination to secure access, and we appreciate the interventions tested through the pilot, including: plan-directed outreach to the prescriber, plan-directed outreach to the pharmacy, and plan-prescribed outreach from the pharmacy to a plan’s help desk.³³

³¹ CMS, “Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” (April 2016, pgs. 78-82), available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2016.pdf>

³² 2016 Announcement and Final Call Letter at 81.

³³ CMS, “2016 Point of Sale (POS) Pilot Event” Webinar held on January 21, 2016.

Still, we have significant concerns about the design of the POS Pilot, leading us to question how useful its findings will be for the development of future policy in this area. In particular, our concerns include:

- Minimal transparency and involvement by multiple stakeholders (including beneficiaries, consumer advocates, pharmaceutical makers, etc.) in the development of the pilot design. Similarly, the only detailed reporting on the POS Pilot was a webinar, making it difficult to fully vet the pilot design and comment on its outcomes. We would strongly prefer a written report or evaluation.
- Lacking outreach to affected beneficiaries to assess how the pilot interventions affected them. At a minimum, we believe it would have been helpful for the pilot participants to reach out to involved beneficiaries to gauge their reaction to the interventions.
- The absence of adequate comparison groups (pilot intervention vs. no intervention) to evaluate successes and challenges. We understand that only one participant in the POS pilot utilized a comparison group. This participant reported a 50% increase in beneficiary access (either to the prescription drug in question or a suitable formulary alternative)—clearly a potential success.³⁴ At the same time, nearly all participants acknowledged time and resource burdens—possibly a potential challenge. CMS reports on both potential benefits and costs associated with the pilot interventions. Yet, without adequate comparison groups, it is difficult to truly assess the relative benefits and costs, both for beneficiaries and for plans.

In general, we believe the potential value of the POS pilot was that it tested interventions to minimize beneficiary burden. Our long-standing concern with the Part D coverage determination process is that it places the responsibility of proving coverage squarely on the shoulders of the beneficiary. In theory, the pilot interventions could significantly minimize that burden, by spreading the time, resources, and energy involved with navigating the coverage determination process among the involved entities.

As such, we are not surprised that the pilot participants reported that the interventions involved significant time and resources. Currently, beneficiaries expend considerable time and resources when turned away at the POS. Further, it is not clear that a plan's time and resources involved with the pilot interventions are all that distinct from the activities a plan is required to engage in through the coverage determination process—it would be helpful to know if the increased cited by the participants was on a case-by-case basis or reflected the fact that not all beneficiaries turned away at the pharmacy counter seek a coverage determination.

Recommendations following from the POS Pilot: CMS identifies two opportunities to prevent situations where beneficiaries are turned away at the pharmacy counter, including encouraging electronic prescribing (e-prescribing) and making formularies more accessible to prescribers. We encourage CMS to pursue strategies to advance these goals. Yet, we do not believe that either will sufficiently address the persistent challenges we observe with Part D coverage determination and appeals processes in the short-term.

While e-prescribing is increasingly utilized among health care providers, research demonstrates that integrated e-prescribing systems that grant physician access to an individual's plan formulary and past medication use have not been uniformly adopted.³⁵ We suspect this level of integration is critical to achieving the ends identified by CMS, namely preventing prescriptions resulting in refusals at the pharmacy counter. Similarly, we support the

³⁴ Id.

³⁵ See: C.M. DesRoches, et al. "Differences Between Integrated And Stand-Alone E-Prescribing Systems Have Implications For Future Use," *Health Affairs*, (December 2010), available at: <http://content.healthaffairs.org/content/29/12/2268.full.html>

goal of making plan formularies more readily available to health care providers. Given existing demands on provider schedules and workloads, we question whether providers will be able to sufficiently gain familiarity with multiple plan formularies for multiple Medicare patients to significantly prevent POS refusals.

CMS also requests input on employing proactive processes to resolve certain POS issues without the enrollee having to request a coverage determination. We believe there may be specific situations where plan-directed outreach directly following a refusal at the POS would serve Medicare beneficiaries well. Among these are:

- Required plan-directed outreach following a POS refusal early in the plan year (such as from January – March), particularly for new enrollees or for those who recently switched plans to minimize denials and appeals for individuals new to a given formulary.
- Required plan-directed outreach to pharmacists to assess whether specific prescriptions drugs are covered under Part B or Part D. We strongly believe that Part D plans should conduct outreach on the beneficiary’s behalf to make these determinations, and we know CMS is similarly committed to ensuring Part B vs. Part D coverage determinations are not assessed through appeals in the MA-PD context.³⁶
- Required plan-directed outreach to prescribers to secure the necessary clinical information to meet prior authorization or step therapy requirements. Meeting these requirements generally requires minimal clinical information, such as a diagnosis or confirmation that another prescription drug has been tried in the past. We suspect the collection of this information would place minimal burden on plans.

We anticipate that other POS refusals, such as securing a formulary alternative or requests for exceptions to prior authorization, step therapy, or quantity limits, are not as well suited for plan-directed outreach. In these situations we would generally expect that a beneficiary would need to consult with his or her prescriber about appropriate next steps to secure a needed medication.

Should CMS develop policies involving plan-directed outreach as described above, we caution the agency against granting broad flexibility to plans in the management of these processes. Without clear requirements and guidelines, it would be difficult to communicate with beneficiaries about how to proceed when refused access at the POS and what to expect from their Part D plan. Further, given persistent shortcomings in plan performance with Part D coverage determinations and appeals, we would be hesitant to support policies unaccompanied by adequate audit procedures and appropriate record-keeping requirements.

In sum, we urge CMS to prioritize solutions that strengthen the Part D appeals process, including the initiatives identified by the agency in the 2016 Announcement and Final Call Letter. While we support CMS’ ongoing efforts to help people with Medicare secure access to medications absent coverage determinations and appeals, we believe it is critically important that the underlying Part D appeals system work properly. It is essential that people with Medicare have the information and tools necessary to navigate this multi-step process.

³⁶ Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Proposed Rule. 79 Fed Reg. (Jan. 10, 2014) at Sec III. C.2