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

Dear Commissioners:

On behalf of the Medicare Rights Center (Medicare Rights), I am writing to inform MedPAC deliberations pertaining to Medicare Part D exceptions and appeals. Medicare Rights is a national, non-profit organization that works to ensure access to affordable health care for older adults and people with disabilities through direct service, education and public policy initiatives. We are grateful for your inquiry into this fundamental issue concerning beneficiary access to needed medications.

We know firsthand the challenges Medicare beneficiaries face when navigating the Part D appeals and exceptions process, as we have counseled thousands of people through this multi-step process. Medicare Rights answers 15,000 Medicare questions from beneficiaries, family caregivers and service providers on our national helpline each year. Through our educational initiatives, we touch the lives of another 65,000 beneficiaries and their families. Additionally, our online learning tool, Medicare Interactive, receives approximately one million visits annually.¹

As an acknowledgement of our expertise with the appeals process, the Centers for Medicare & Medicaid Services (CMS) lists our organization alongside resources including 1-800-MEDICARE and Elder Care Locator on its standardized notice of coverage denial, which Part D plans are required to use.² Our organization was again listed as a beneficiary resource on a recently issued model integrated denials notice developed for use by health plans serving dually eligible beneficiaries.³ Below, we detail our experience serving people with Medicare who seek an appeal as well as our recommendations on how to strengthen the Part D exceptions and appeals process.

¹ Visit "Medicare Interactive" at: <http://www.medicarerights.org/medicare-interactive/>

² CMS, "Notice of Denial of Medicare Prescription Drug Services," (last revised February 2013), available at: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10146.pdf>

³ Center for Medicare and Medicaid Services, "Integrated Denial Notice Form," (issued August 2013), available at: <http://www.cms.gov/Medicare/Medicare-General-Information/BNI/MADenialNotices.html>

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Medicare Part D Exceptions and Appeals—Recounting the Beneficiary Experience

Each year, Medicare Rights receives up to 5,000 calls from people with Medicare, family caregivers and service providers seeking help with Medicare appeals and coverage-related issues. Often, these callers are beneficiaries refused a prescribed medication at the pharmacy counter. An appeal is not always the appropriate path for these callers, but for those who must request an appeal to obtain a needed medication, we find that the current process is fraught with needless steps and significant risks.

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 their drug plan for the denial reason. Beneficiaries often face long call wait times and inconsistent customer service when trying to obtain this information.

Second, 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 prescription drug plan, entitling 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.

Finally, and most importantly, we find that as the appeals process unfolds, many beneficiaries experience delays accessing needed medications. Others who leave the pharmacy counter empty-handed bypass the formal appeals process, paying for the full cost of the prescribed medication, purchasing one or two pills at a time to get by, seeking drug samples from the prescribing physician, which may or may not be readily available, or simply going without their medication altogether.

In short, an unwieldy and overly burdensome appeals process increases costs for beneficiaries and their families and threatens the health of people with Medicare. The needs of a growing aging population demand that the Medicare Part D exceptions and appeals process be both clarified and streamlined.

Recommendations to Improve Part D Exceptions and Appeals

Provide clearer information, sooner. As noted above, a Medicare beneficiary first learns that a drug is denied when a prescription is refused at the pharmacy counter. We believe that this represents a critical moment for educating beneficiaries about how to pursue the appropriate path forward—to appeal the

plan decision or to pursue other avenues for obtaining a needed medication with the aid of their pharmacist or prescribing physician. Having information about the reason a drug is refused at the point-of-sale is critical to this decision-making process. As such, we recommend:

- **Adding individually tailored language to the existing standardized notice at the pharmacy.** In addition to the plan contact information, including phone and online access, and clear guidance on the next steps in the appeals process, the denial notice should include a clear explanation of the reason the drug is refused.

Streamline the process. If an appeal is appropriate, Medicare beneficiaries must navigate several needless and burdensome steps before an appeal is officially filed. Under the current scheme, plans are allowed three opportunities to refuse payment for a prescribed medication: at the pharmacy counter, through the coverage determination and again through 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.

We appreciate several steps recently made by CMS to reduce barriers to the appeals process, including eliminating the need for prescribing physicians to submit written authorization to pursue higher levels of appeal and enhancing online access to appeals forms and procedures. Yet, more comprehensive reform is needed. We believe that Medicare beneficiaries would be best served by initiating the coverage determination request at the pharmacy counter when the prescription is presented. Although not a consistent practice, we know that some pharmacists already take it upon themselves to help explain the appeals process to a beneficiary when payment is refused on a prescription. As such, we recommend:

- **Combining the point-of-sale refusal with the formal request for a coverage determination.** 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 by explicitly stating why the drug is not covered while also expediting the appeals process for those who need it.

While we believe that our recommended framework would be ideal for Medicare beneficiaries, we support considering other avenues or interim steps to streamline the appeals process. Concepts worth exploring include the following: eliminating the redetermination step in the Part D appeals process; requiring a pharmacy counter refusal to trigger a plan inquiry with the prescribing provider; and allowing and encouraging pharmacists, with plan technical support, to counsel their patients regarding denial reasons and appeal rights.

In sum, we strongly believe that the responsibility for pursuing appeals should be shared by the plan, the pharmacist, the prescribing practitioner and the beneficiary—as opposed to the current system requiring sole responsibility on the part of the beneficiary.

Data Collection and Transparency

As was discussed during MedPAC’s public meeting, limited data is made publicly available on the beneficiary experience and plan performance with appeals. Available data captures trends only after the appeal reaches review by the Independent Review Entity (IRE)—the third formal tier of the appeals process, and the first time that a beneficiary appeal is reviewed by an entity other than the drug plan.⁴ As described above, the appeals process involves multiple steps and multiple parties, including the plan, the beneficiary, the pharmacist and the prescribing physician, ahead of the IRE.

Questions remain about how many beneficiaries are able to successfully process an appeal and how beneficiaries cope with delayed or limited access to prescribed medications long before the appeal reaches the IRE. We know that some beneficiaries simply lack the know-how to follow-through with the appeals obstacle course, and others do not see prescribing physicians able or willing to provide the needed support for a formal appeal. We suspect that lower-income beneficiaries struggle most with this process given that many of our Extra Help clients would rather switch their drug plan through an allowed Special Enrollment Period (SEP) rather than request an appeal. In short, based on our helpline experience, we believe that many people with Medicare do not successfully follow through with a needed appeal; yet, without concrete data we cannot measure this trend.

We believe CMS should measure plan performance at all levels of the appeal, beginning with the prescription refusal at the point-of-sale, and this plan-level data should be made public. Access to this information will allow CMS, members of Congress, consumer advocates and other stakeholders to better understand beneficiary- and plan-related concerns and assess areas for needed improvement.

We encourage MedPAC to examine available data sets and to recommend greater transparency and enhanced data collection by CMS on plan-level appeals. Further, we are encouraged that MedPAC intends to more closely examine the troubling trends noted during the public meeting concerning the notable number of successful IRE appeals regarding late enrollment penalties for Part D beneficiaries.

MedPAC Proposal on Extra Help Cost Sharing—An Appeals Overhaul is Needed

We understand that MedPAC is examining this issue as part of its approved recommendation to alter copayments for brand name and generic medications for beneficiaries enrolled in the Low-Income Subsidy of Medicare Part D (or Extra Help).⁵ We strongly support eliminating copayments for generic medications within Extra Help to encourage generic drug use and enhance medication adherence among these low-income beneficiaries, many of whom have multiple chronic conditions and take numerous prescription drugs.

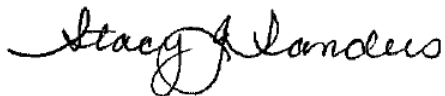
⁴ Presentation by Sokolovsky, L., Suzuki, S. and L. Metayer, “Part D exceptions and appeals” (September 2013), available at: <http://www.medpac.gov/transcripts/part%20d%20exceptions%20&%20appeals.pdf>; CMS, “Fact Sheets: Part D Reconsideration Appeals Data, Part D Fact Sheets CY 2011” (2011), available at: <http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Reconsiderations.html>

⁵ MedPAC, “Report to the Congress: Medicare Payment Policy, Chapter 13: Status Report on Part D, with focus on beneficiaries with high drug spending” (March 2012), available at http://www.medpac.gov/chapters/Mar12_Ch13.pdf/

We remain concerned, however, about the effect of MedPAC's proposal on access to needed brand name medications for vulnerable Medicare beneficiaries. This concern stems largely from our experience with Part D exceptions and appeals. Absent reform of the current appeals system, we believe beneficiaries who require brand name drugs as a medical necessity would experience barriers to access if these copayments were increased.

We applaud MedPAC for examining the Medicare Part D appeals and exceptions process and welcome the opportunity to share input on forthcoming recommendations. Thank you for the opportunity to provide comment.

Sincerely,

A handwritten signature in black ink that reads "Stacy Sanders". The signature is written in a cursive, flowing style.

Stacy Sanders
Federal Policy Director
Medicare Rights Center