March 6, 2015

VIA ELECTRONIC SUBMISSION
AdvanceNotice2016@cms.hhs.gov

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Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter

To Whom It May Concern:

The undersigned organizations are pleased to submit comments on the draft 2016 Part C and Part D call letter, specifically focused on the agency's proposals concerning Medicare Advantage (MA) and Part D appeals. Our organizations share a commitment to advancing the health and economic security of people with Medicare and their families. If you have questions or require additional information, please contact Stacy Sanders, Federal Policy Director of the Medicare Rights Center, at ssanders@medicarerights.org or 202-637-0961. Thank you for the opportunity to provide feedback on these important policy intiatives.

Attachment VI: 2016 Draft Call Letter

Making the Exceptions and Appeals Processes More Accessible for Beneficiaries: We applaud CMS for its commitment to improving the Medicare Advantage (MA) and Part D appeals processes for Medicare beneficiaries, family caregivers and health care providers. Like CMS, we are deeply concerned by the findings of the agency's recent audits of plan sponsors, which revealed significant challenges related to organization/coverage determinations, appeals and grievances as well as formulary and benefits administration. [1]

We are also deeply troubled by the high incidence of CMS sanctions involving plan sponsors' failure to comply with MA and Part D requirements concerning organization/coverage determinations, appeals and grievances. In 2013, CMS notes that nearly all enforcement actions (89%) stemmed from non-compliance resulting in "…inappropriate delays or denials of access to health services and medications for enrollees."[2]

Similarly, we continue to be alarmed by CMS' annual data on Part D reconsiderations—the third level of decision and the first level of review conducted by an Independent Review Entity (IRE). Among reconsiderations, CMS found that an IRE reversed 32% of plan-level decisions in 2013. Importantly, IRE reversal rates for cases involving

[1] 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
[2] CMS, "The 2013 Part C and Part D Program Annual Audit and Enforcement Report," (Issued by the Medicare Parts C & D Oversight and Enforcement Group; October 16, 2014), available at: http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html

utilization management controls are also unreasonably high—47% in 2013.[3] These reversal rates, in concert with CMS' audit findings, underscore the need to strengthen the Part D appeals process. It is essential to ensure that accurate decisions are made at the earliest possible stage to eliminate unnecessary delays in access to needed medications.

CMS' findings are generally reflective of what our organizations continue to observe among Medicare beneficiaries who are denied access to a medication or for whom a specific medication's cost sharing proves overly burdensome. Beneficiaries 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.[4]

Along these same lines, upon review of the available qualitative and quantitative research on Part D appeals, the Medicare Payment Advisory Commission (MedPAC) recently determined 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."[5] We concur with MedPAC's conclusions, and we support CMS' interest in pursuing multiple avenues to achieve this end.

In keeping with CMS' stated goals in the draft 2016 call letter, we urge CMS to establish a multi-stakeholder workgroup (including, but not limited to, Part D plan enrollees, Medicare beneficiary advocates, pharmacists, plan sponsors, pharmacy benefit managers and pharmaceutical manufacturers) to work on developing a streamlined Part D appeals process that is initiated when a request for coverage of a prescription drug is denied in whole (or in part) at the pharmacy counter. We also encourage CMS to engage in a similar dialogue with multiple stakeholders on potential improvements to the MA appeals process.

We strongly encourage CMS to engage in these discussions as quickly as possible to ensure that the future improvements named by CMS in the draft 2016 call letter can be adequately assessed by all affected stakeholders. We appreciate that there are important technical considerations that must be weighed in order to implement some of the suggested improvements, and we believe a multi-stakeholder dialogue would be best suited to engage on these issues. Again, we applaud the agency's willingness to consider reforms to the MA and Part D appeals system with the aim of improving the accessibility of these processes for beneficiaries. Below we provide more detailed comments on the provisions included in the draft 2016 call letter.

Coverage Denial Notices and Requests for Clinical Documentation

Denial Notices: We strongly support and appreciate CMS' reminder to MA organizations and Part D plan sponsors about the information required in denial notices, specifically involving the reason for the denial, the

[3] CMS, "Fact Sheet: Part D Reconsideration Appeals Data – 2013" (2013), 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, leading 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 scrutiny.

[4] 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

[5] 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

applicable Medicare or plan coverage policy and any specific coverage requirements that must be met to obtain coverage. The exact rationale for denials is critical to the ability of Medicare beneficiaries and health care providers to understand their situation, decide next steps and advocate effectively. We urge CMS to include this language in the final 2016 call letter.

Requesting Clinical Documentation: We strongly support the requirements set forth in the draft 2016 call letter clarifying MA organization and Part D plan sponsor obligations to seek out clinical information when needed to process a coverage request. We also support CMS' requirement that plans adequately document attempts made to secure needed clinical information. Presently, Medicare beneficiaries must serve as a de-facto intermediary between their MA or Part D plan and their health care provider, even though many people with Medicare lack the aptitude to perform this role. The resulting breakdown in information-sharing likely contributes to fewer appeals and higher rates of denials, delays and other inefficiencies. In the interest of efficiency and fairness, we urge CMS to finalize these requirements for MA and Part D plan sponsors in the final 2016 draft call letter.

Future Improvements: We strongly support CMS' suggested improvements to the Part D denial notice (Form CMS-10146) as well as CMS' strong encouragement that Part D plan sponsors begin implementing these improvements as quickly as possible. We expect that these enhancements to the Part D denial notices—namely the requirement that the denial reason cite to the CMS-approved plan formulary or other Medicare rule as a basis for the decision—will significantly ease the burden on beneficiaries and health care providers to provide adequate, actionable information when a beneficiary appeal is warranted. Additionally, we strongly encourage CMS to move forward with the agency's plans to include these same notice changes for MA denial notices.

Still, we believe these requirements would be further strengthened by a CMS review of the "enrollee-friendly" or "free text" portion of the Part D denial notice. We continue to observe that this "free text" section, largely intended for Medicare beneficiaries, causes significant confusion. In some cases, the content proves to be incomprehensible to the beneficiary. On this point, it is important to note that most Medicare beneficiaries may not be familiar with technical or legal language describing a plan denial.

To further build on the improvements recommended by CMS, we encourage the agency to make available best practices on communicating plain language reasons to explain denials (i.e., off-formulary, prior authorization, step therapy, quantity limits, etc.) in the "free text" section of the Part D denial notice. Given that the "free text" portion is directed to older adults and people with disabilities, it is critically important that this language is *both accurate*—meaning it matches the plan formulary, coverage rules and the more detailed section described above—*and easy to understand*—meaning it is written in line with the education and health literacy levels of most beneficiaries.

<u>Improved Information at the Point of Sale</u>

First, we commend CMS' willingness to explore improvements to the pharmacy counter notice (Form CMS-10147), and we urge the agency to explore this possibility as quickly as possible in consultation with multiple stakeholders. Medicare beneficiaries refused access to a medication at the pharmacy counter experience this "turning away" 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.

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 point of sale, Part D enrollees and their health care

providers will be better equipped to determine the best course of action for the beneficiary's health—whether that involves securing a different prescription, waiting the appropriate time period for a refill or filing an exception request with the health plan.

We appreciate that pursuing this option will involve working in collaboration with the National Council of Prescription Drug Programs (NCPDP). We encourage CMS to assess the potential of advancing this change for specific types of denials or other pharmacy edits, such as the application of any number of utilization management tools. We strongly encourage CMS to engage in a multi-stakeholder conversation on pursuing improvements to the current pharmacy counter notice.

Additionally, we encourage CMS to carefully explore a concern not addressed in the 2016 draft call letter related to the pharmacy counter notice. Specifically, we urge CMS to assess how frequently and consistently the pharmacy counter notice is delivered to Medicare beneficiaries denied access to prescription drugs as well as those who express concern with the coinsurance or copayment for a given medication. Only in recent years has the delivery of this notice been required by CMS of plan sponsors, and in turn required of plan sponsors' network pharmacies.

We continue to hear from Medicare beneficiaries who claim they have not received this notice, meaning these individuals lack critical information about how to pursue a coverage determination and their appeal rights. Monitoring the delivery of the pharmacy counter notice is important, both to ensure beneficiary access to needed medicines and sponsor compliance with CMS rules.

Second, we applaud CMS' willingness to explore allowing the presentation of a prescription to serve as the request for a coverage determination. As noted above, it is conceptually very difficult for a beneficiary to parse the difference between a health plan's refusal at the pharmacy counter and a formal denial resulting from a 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, first by explicitly stating why the drug is not covered and, second, by expediting the appeals process for those who need it. As such, we continue to believe this course of action is in the best interest of beneficiaries, their families and their health care providers.

Again, we appreciate that potentially implementing this process, either for some or all claims not paid at the pharmacy, will involve technical considerations that should be explored among multiple parties. We ask CMS to fully explore how to implement this proposal for each reason that a prescription drug may be refused payment at the point of sale (i.e., non-formulary, prior authorization, step therapy, quantity limits, refill too soon, inadequate information from a prescriber, potential adverse interaction, etc.). As noted above, we strongly encourage CMS to engage in an open and ongoing dialogue with all stakeholders about this option and others that might be pursued to streamline and simplify the Part D appeals process for Medicare beneficiaries, caregivers and providers.

Although not directly addressed in the draft 2016 call letter, in addition to solutions related to payment refusals at the point of sale and denials of coverage, we encourage CMS to explore policy changes specific to beneficiary requests for tiering exceptions. We regularly hear from older adults and people with disabilities desperate to reduce the cost of medications who are altogether unaware of their right to request a tiering exception. We fear only those Medicare beneficiaries who are particularly savvy or who have the assistance of a trained counselor are positioned to successfully request a tiering exception. Increased beneficiary and health care provider education about when tiering exceptions are available and appropriate is sorely needed. At a minimum, we encourage CMS to require plan sponsors to provide such training to network providers, including pharmacists, physicians and other prescribers.

Expanded Data Collection for Part D Appeals

We strongly support CMS' openness to developing a more rigorous Part D appeals tracking system. Like CMS, we are concerned that the available data on Part D coverage determinations, redeterminations and reconsiderations does not adequately reflect the full range of beneficiary experiences with the process. We strongly supported CMS' 2014 release of plan-reported data on MA and Part D coverage determinations, appeals and grievances through a public use file.[6] Yet, like CMS, we agree that this information is insufficient. In 2014, MedPAC also expressed concern about the transparency of plan-level decisions and the availability of concrete data on the Part D appeals process.[7]

We share CMS' alarm with the high reversal rates of plan decisions at the redetermination level (80%) in CY2013, coupled with an extremely low rate of beneficiary appeals (17%).[8] And, as noted above, we are equally concerned with the high rate of reversals of plan decisions by the IRE, at the reconsideration level. As described above, Medicare beneficiaries who leave the pharmacy counter empty-handed may never access the formal appeals process. This can result in a beneficiary 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 a prescribed medication altogether. Given this experience, we are very supportive of enhanced data collection on all steps of the Part D appeals process.

As such, we strongly encourage CMS to expand the scope of its proposed tracking system. For Medicare beneficiaries who experience difficulty securing a needed prescription drug, the process ultimately begins at the pharmacy counter—*not with the request for a coverage determination*. CMS currently requires plan sponsors to report on pharmacy transactions, including claims paid and rejected, and requires data collection on various utilization management tools and other reasons for nonpayment.[9] We strongly encourage CMS to develop tracking that begins with the refusal at the pharmacy counter and ends with the Administrative Law Judge (ALJ) or Medicare Appeals Council (MAC). We believe that tracking on this level would allow CMS to gauge how often beneficiaries are able to secure prescription drugs through informal mechanisms, such as through the assistance of a prescriber, as opposed to through the formal appeals process.

In closing, we enthusiastically commend CMS for the content included in the draft 2016 call letter on MA and Part D appeals. We look forward to an ongoing dialogue with the agency on these issues. Thank you for the opportunity to provide comment.

Sincerely,

American Association on Health and Disability
California Health Advocates
Caregiver Action Network

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

[7] 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

[8] CMS, "Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter," (February 20, 2015; pg. 80), available at: http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2016.pdf

[9] CMS, "Medicare Part D Reporting Requirements," (Effective January 1, 2014), available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CY2014PartDReporting_Requirements_V022514.pdf

Center for Medicare Advocacy, Inc.
Epilepsy Foundation
Justice in Aging (formerly National Senior Citizens Law Center)
Lupus Foundation of America
Mandy Pino Center
Medicare Rights Center
National Academy of Elder Law Attorneys (NAELA)
National Association of Professional Geriatric Care Managers
National Committee to Preserve Social Security and Medicare
National Community Pharmacists Association (NCPA)
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