



Getting Medicare right

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VIA ELECTRONIC SUBMISSION

AdvanceNotice2017@cms.hhs.gov

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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

The Medicare Rights Center (Medicare Rights) is pleased to submit comments on the 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 (2017 Advance Notice and Call Letter). Medicare Rights is a national, nonprofit consumer service 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. Medicare Rights serves over two million Medicare beneficiaries, family caregivers, and professionals through its national helpline and educational programming annually.

If you have questions or need additional information, please contact Stacy Sanders, Federal Policy Director, at ssanders@medicarerights.org or 202-637-0961 and Casey Schwarz, Policy and Client Services Counsel, at cschwarz@medicarerights.org or 212-204-6271. Thank you.

Attachment II. Changes in the Part C Payment Methodology for CY 2017

Section A. MA Benchmark, Quality Bonus Payments and Rebate: We support the payment methodologies outlined in the 2017 Advance Notice and Call Letter. These methods are consistent with applicable law, particularly the Affordable Care Act (ACA) changes to bring Medicare Advantage (MA) plan payments in line with costs under the traditional Medicare program. We continue to support these policies, which are critical to stabilizing the fiscal health of the Medicare program and ensuring efficient spending of taxpayer dollars. CMS' proposed payment rates are reflective of these policies, and we support their implementation.

We note that 2017 marks the first year that all counties will be paid based entirely on the fee-for-service rate, an important milestone in shifting to fair payment strategies. Importantly, we continue to observe that people with Medicare have ample choice and benefit from continued stability in the MA plan landscape. Still, we urge CMS to continue to closely monitor the MA market to ensure that plans are optimally serving people with Medicare.

Section G. MA Employer Group Waiver Plans: CMS proposes to waive the bidding requirements for MA Employer Group Waiver Plans (EGWPs) and to pay these plans using an alternative payment mechanism. According to CMS, these changes are intended to reduce administrative burdens on employer plans and to more accurately capture EGWP costs by eliminating existing incentives to submit bids that are higher than actual projected costs.

These arguments are supported by findings from the Medicare Payment Advisory Commission (MedPAC). According to MedPAC, average Medicare payments to EGWPs are 106 percent of traditional Medicare costs for comparable beneficiaries. CMS notes that while EGWPs tend to have healthier, lower-cost enrollees than other MA plans and face lower administrative costs related to enrollment and marketing, on average, their bids are higher. MedPAC has previously recommended that CMS take steps to determine payments for EGWPs in a manner more consistent with how other MA plans are paid.¹

Given this, we generally support the proposed changes to EGWP waivers and payments. Yet, we are concerned about the abrupt impact these changes may have on retiree health benefits. For example, under the revised payment model, EGWPs would no longer be able to pay the Part B premium on behalf of enrollees and may not be able to offer the supplemental benefits that their enrollees have come to depend upon.

CMS argues that this change is appropriate because EGWPs do not need to use supplemental benefits to attract enrollees (as other MA plans do), but benefits such as vision, dental, and enhanced Part D formularies are not merely marketing tools—they are important protections against significant costs and unmet medical needs. As such, we encourage CMS to consider ways to mitigate the effects of the proposed changes, such as by permitting EGWPs to separately reimburse members for their Part B premiums or by phasing in reductions in payments.

Section H. CMS-HHC Risk Adjustment Model for CY 2017: CMS proposes to alter the CMS-HHC risk adjustment model for 2017 by segmenting the community model population into six groups (including non-dual aged, non-dual disabled, full benefit aged, full benefit disabled, partial benefit aged, partial benefit disabled) and by updating disease-disease interactions. We support the proposed adjustments, which are intended to improve the accuracy of risk adjustment for full-benefit dually eligible and disabled individuals.

We expect improved accuracy of risk adjustment will result in more equitable payments to plans that serve high proportions of full-benefit dually eligible and disabled individuals. Accurately accounting for the challenges that impede the efficient provision of competent care for vulnerable Medicare beneficiaries is important to ensuring that plans can fulfill their obligation to provide coordinated, high-quality care.

At the same time, we understand this correction will result in lower than historical payments to plans that serve a large proportion of partial-benefit dually eligible beneficiaries—those enrolled in Medicare Savings Programs (MSPs). These programs are traditionally under-enrolled, and many older adults and people with disabilities

¹ MedPAC, “Report to The Congress: Medicare Payment Policy” (March 2014), available at: http://medpac.gov/documents/reports/mar14_entirereport.pdf

remain altogether unaware of the Part B premium and cost sharing assistance that may be available to them.² We appreciate the concern (as described in comments from some stakeholders in October 2015) that the proposed change may mean that some plans are less likely to identify and offer application assistance to enrollees who may be eligible for MSPs.³

While important, these outreach and enrollment benefits are not sustainable if they are only possible as a result of overpayment and inaccurate risk adjustment. As such, we believe it is essential to adequately fund and support community-based organizations that screen, conduct outreach, and assist beneficiaries in applying for MSPs, such as the State Health Insurance Assistance Programs (SHIPs). Additionally, we encourage CMS to work with Congress to expand access to MSPs, pursuing both the recommendations identified in the President's FY2017 budget as well as legislative reforms to relax income thresholds, eliminate asset tests, and streamline enrollment and application systems.⁴

Section I. Medicare Advantage Coding Pattern Adjustment: CMS proposes setting the MA coding adjustment factor to the statutory minimum of 5.66 percent. This adjustment factor is designed, in part, to offset higher payments made to MA plans as a result of more comprehensive diagnoses code recording in MA than is routinely done in traditional Medicare.

CMS attributes the higher level of reported diagnoses to a variety of plan motivations including “plans seeking to better understand the health status of their enrollees so they can provide better care [and] plans reporting more diagnoses for enrollees to generate higher revenue.”⁵ Motivation aside, these coding behaviors result in the same outcome: higher payments to MA plans than would be the case if plans coded similarly to health care providers in traditional Medicare. According to MedPAC, average risk scores grew nine percent faster in MA than in traditional Medicare for comparable beneficiaries.⁶

The cost of this “upcoding” is significant. According to CMS, a one percent increase in MA risk scores due to differential coding in 2017 would increase MA payments by about \$2 billion.⁷ We agree that CMS should continue to closely monitor coding intensity trends but further urge that the agency use its authority to fully offset the impact of differential coding by increasing the coding intensity adjustment. MedPAC findings indicate that the statutory minimum coding adjustment, together with other actions CMS is undertaking, are likely insufficient to fully offset current coding intensity trends.⁸

In addition, we strongly recommend that CMS reconsider excluding in-home health assessments from risk score calculations unless they are later confirmed in treatment settings, as proposed in the 2016 Advance Notice and

² MedPAC, “Report to the Congress: Medicare Payment Policy,” (March 2008), available at: http://www.medpac.gov/documents/reports/Mar08_Ch05.pdf

³ Comments to “Proposed Changes to the CMS-HCC Risk Adjustment Model for Payment Year 2017” (October 2015), available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Risk-Adjustors-Items/RiskProposedChanges.html>

⁴ HHS, “FY2017 Budget in Brief, Strengthening Health and Opportunity for All Americans” (February 2016, pgs. 99-100), available at: <http://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf>

⁵ 2017 Advance Notice and Call Letter at 42.

⁶ MedPAC, “Medicare Advantage: Status Report,” (December 10, 2015), available at: <http://medpac.gov/documents/december-2015-meeting-presentation-the-medicare-advantage-program-status-report.pdf?sfvrsn=0>.

⁷ 2017 Advance Notice and Call Letter at 41.

⁸ See: MedPAC, “Report to the Congress: Medicare Payment Policy,” (March 2015), available at: http://medpac.gov/documents/reports/mar2015_entirereport_revised.pdf?sfvrsn=0; and Johnson, A, “Medicare Advantage Coding Intensity and Health Risk Assessments,” (MedPAC, October 2015), available at: <http://medpac.gov/documents/october-2015-meeting-presentation-medicare-advantage-benchmarks-.pdf?sfvrsn=0>

Call Letter.⁹ We encourage CMS to carefully examine at-home risk assessments to ensure that the services provided to beneficiaries through these visits are meaningful and effective, and are not simply a means for collecting risk adjustment diagnoses without ensuring that meaningful follow-up care is delivered.

Attachment III. Changes in the Payment Methodology for Part D for CY2017

Section G. Part D Calendar Year Employer Group Waiver Plans: CMS proposes to make prospective reinsurance payments to all Employer Group Waiver Plans (EGWPs) based on the average actual reinsurance amounts paid to EGWPs in 2014. We appreciate the burden that high prescription drug costs place on Part D EGWPs, and we support CMS' efforts to prevent solvency and access problems for these plans and their enrollees by making limited prospective reinsurance payments.

Attachment VI. CY2017 Draft Call Letter

Section I – Parts C and D

Annual Calendar: As in prior years, CMS indicates that MA and Part D plans should disseminate both the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) by September 30th. We continue to encourage CMS to revisit its prior recommendation to require separate mailings of the ANOC and EOC for MA plans, and we believe this would be similarly beneficial for Part D plans.¹⁰ The EOC is a long and detailed document, and we often observe that beneficiaries find reviewing the EOC a daunting experience. By contrast, the ANOC is a streamlined tool designed to help beneficiaries determine whether or not switching to another MA plan, Part D plan and/or traditional Medicare during the open enrollment period would be a beneficial choice. Separating the mailings would allow beneficiaries to focus their attention on the ANOC.

At the same time, we continue to believe that improvements to the ANOC are long overdue. We often hear from Part D and MA enrollees who are adversely affected by unanticipated plan changes early in the plan year. We continue to advocate for an individualized MA and Part D ANOC to better serve beneficiary needs, specifically one that details which specific providers are leaving a plan network, which specific prescription drugs are no longer on the plan formulary, where utilization management tools will be newly applied, and so forth—customized according to the actual providers, services, and prescription drugs that an individual utilizes.

We strongly urge CMS to consider opportunities to tailor these notices to individual information needs. At a minimum, we suggest that CMS solicit input from multiple stakeholders on recommendations to improve the ANOC, EOC and other standardized materials used during the annual election period.

Incomplete and Inaccurate Bid Submissions: We support CMS' continued close scrutiny of bid submissions. At the same time, we encourage CMS to more regularly and thoroughly review plan sponsors' bids for compliance with minimum provider access standards, formulary adequacy, and benefit parameters. Ensuring that plan sponsors meet these minimum standards—at the outset of each year—is critical to ensuring that Medicare beneficiaries have access to appropriate and adequate coverage.

⁹ 2016 Advance Notice and Call Letter at 139.

¹⁰ 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) pp. 1918-2073 (to be codified at 42 CFR Parts 409, 417, 422, et al.)

Contracting Organizations with Ratings of Fewer Than Three Stars in Three Consecutive Years – Timeline for Application of Termination Authority: We commend CMS for exercising the agency’s authority to terminate consistently low-performing health plans in 2017. We expect this will enhance public confidence in the utility of the Star Ratings Program, drive quality improvement in the MA program, and safeguard the health and well-being of people enrolled in MA plans.

We want to emphasize the importance of providing clear and timely notice to affected enrollees when their plans are terminated for this or any other reason. These notices should inform beneficiaries of their full range of options and offer the support necessary to promote informed decision-making. Detailed notices, including information about access to a Special Enrollment Period (SEP) and Medigap enrollment rights, should be developed for enrollees who are affected by low-performance related terminations. In particular, enrollees with unique needs, such as those in Special Needs Plans (SNPs), should receive notice and information that specifically addresses their options.

Enhancements to the 2017 Star Ratings and Beyond

A. & B. Changes to Measures for 2017 and Removal Measures from Star Ratings: We support the proposed modifications to the listed measures, including methodological changes and removals.

C. Data Integrity: Like CMS, we agree that data integrity is essential to the safeguard the Star Ratings Program. We support increased scrutiny of plan data, particularly that related to the Medication Therapy Management (MTM) program and any plan activities that could adversely affect beneficiary access to MTM.

D. Impact of Socio-economic and Disability Status on Star Ratings: CMS proposes to adjust Star Rating scores for socio-economic and disability status in response to repeated comments from plan sponsors who suggest that enrollment of a high percentage of dually eligible (DE) beneficiaries or those who receive the Low-Income Subsidy (LIS) limits a plan’s ability to achieve high Star Ratings. We commend the research and careful consideration that CMS has undertaken to address this issue, particularly the agency’s commitment to ensuring any policy development on this topic is data driven.

Like CMS, we are aware of the substantial, ongoing work underway at the Department of Health and Human Services (HHS), their measure steward partners, the Institute of Medicine, and the National Quality Forum (NQF) to carefully evaluate these issues. With that in mind, we do not believe changes to Star Ratings intended to adjust for socio-economic or disability status should be made until such work is complete and the evidence supports the adjustment. To do otherwise would undermine CMS’ commitment to a rigorous, data-driven process.

Instituting an adjustment—even an interim one—before the causal relationships are fully understood carries significant risk. CMS must preserve the credibility of the Star Ratings Program, namely by ensuring the Star Ratings reflect the actual quality of care delivered by a given a health plan. To accomplish this goal, CMS should not pursue adjustments to the Star Ratings that risk masking disparities in care quality or creating perverse incentives for poor-performing plans to seek out vulnerable populations.

CMS identifies two potential disparities/comparators: (1) the difference between the Star Ratings results for plans with a high number of DE/LIS enrollees and other plans with a lower percentage of DE/LIS enrollees

(referred to as “between-contract” differences) and (2) the difference between the Star Ratings scores for LIS/DE individuals and other individuals within the same plan (referred to as “within-contract” differences). CMS does not propose to adjust scores for between-contract differences, reasoning that doing so risks masking true differences in quality that may exist between plans if LIS/DE beneficiaries are more or less likely than others to enroll in certain plans. This reasoning is sound and we support CMS’ determination that the agency should not adjust for between-contract differences.

Yet, CMS reasons that within-contract differences are appropriate targets for adjustment. We question the assumption that a health plan necessarily provides the same quality of care to all enrollees, and we are concerned that CMS’ proposed adjustments may mask differences in performance that are within the control of the plan and unrelated to the DE/LIS status of the plan population. In addition, we note that some plans with high enrollment of DE/LIS beneficiaries perform well in the Star Ratings Program.

We encourage CMS to conduct further study on measures where within-contract differences were found. For example, if quality scores for measures that evaluate screening and preventive services are lower among enrollees with a certain disability status, CMS should ensure that the affected plans had accessible in-network providers of sufficient numbers such that the disparity was not caused or exacerbated by contracting decisions. CMS should not adjust quality measures before ensuring that the differences eliminated by the adjustments are truly caused by circumstances outside of the plan’s control. To do otherwise could discourage careful thinking and other innovations on how to deliver the highest quality care to specific groups.

Should CMS move ahead with one of the proposed adjustment schemes, we suggest the following:

- **Develop a plan to phase out the adjustment:** We appreciate that CMS is presenting the proposed adjustment as an interim proposal, until the measure owners can update specific measures. Yet, we urge CMS to identify a timeline to phase out the proposed risk adjustment multiplier. Once introduced to the system, we believe the adjustments will be difficult to undo without clear expectations on a timeline. As such, we encourage CMS to identify a plan for the termination of the adjustment.
- **Engage multiple stakeholders:** We strongly encourage CMS to establish a multi-stakeholder workgroup (including, but not limited to beneficiaries, consumer advocates, health plans, health care providers, and measure developers) to evaluate all of the evidence and consider whether adjustments to Star Ratings are required to account for higher enrollment of LIS/DE beneficiaries.

If this group determines adjustments are required, they should be charged with examining the beneficiary impact of any such proposed changes to Star Ratings and be required to develop a plan to ensure disparities will not be masked or exacerbated. CMS and this multi-stakeholder group should also closely monitor whether high performing plans with high enrollment of individuals with low socioeconomic status witness drop-off or changes in performance on quality measures after the adjustment.

- **Publish both adjusted and un-adjusted scores:** In order to promote understanding of the range and degree of the change in score created by this policy, we urge CMS to make both sets of scores available to the public. In particular, we suggest that CMS publish only the non-adjusted scores on Plan Finder, utilizing the adjusted measures only for the purposes of establishing bonus payments. In addition, we suggest that CMS carefully consider which of the two measure sets should be used for the purposes of determining beneficiary Special Enrollment Periods (SEPs) and how best to communicate about that measure set to beneficiaries.

E. 2017 CMS Display Measures: We support the revised and new 2017 display measures identified by CMS.

Forecasting to 2018 and Beyond

F. New Measures: We applaud CMS for considering the listed measures for future use in the Star Ratings Program. In particular, we are encouraged by the development of measures on care coordination for MA plans.

G. Changes to Existing Star Ratings and Display Measures and Potential Future Changes: We support the future changes identified by CMS for Star Ratings and Display measures. In particular, we applaud CMS for identifying needed changes to the methodology for assessing Medicare Plan Finder pricing accuracy.

We continue to hear from Part D enrollees who report notable differences in cost sharing for prescription drugs between what was displayed on Plan Finder and what they paid at the pharmacy counter. As such, we support changes that would capture additional categories of day supply as well as modifications to assess both how much and how often pharmacy counter costs exceed Plan Finder display costs, for use in both the Star Ratings and Display measures in 2018.

Medicare Part C & D Program Audits: We continue to be concerned by MA organization and Part D plan sponsor performance related to coverage determinations, appeals, and grievances, as reported through the agency's audits and enforcement actions. We appreciate that CMS has been transparent about plan deficiencies by posting the enforcement letters. Yet, we urge the agency to consider additional ways to spotlight these findings, such as by requiring a public statement or press release by MA organizations and Part D plan sponsors when a plan audit results in enforcement action(s). Such statements should be displayed prominently on plan websites and on Plan Finder.

We also strongly encourage CMS to publically release more granular and detailed audit results. CMS' summary reports are helpful, but they do not capture the information needed to formulate targeted responses or allow stakeholders to accurately identify problem areas across plans—like, for example, the high rate of auto-forwarded cases to the Independent Review Entity (IRE) resulting from plan failures to follow redetermination timelines, as described in the 2017 Advance Notice and Call Letter.

We continue to strongly support CMS' pilot of additional audit modules on MTM and the separate and more comprehensive audits of provider network adequacy and provider directories. We continue to hear directly from Medicare beneficiaries on both of these issues. As noted below, we share CMS' ongoing concerns that the MTM program is not fulfilling its promise and Medicare beneficiaries are not benefiting fully from these services.

Medicare Part C & D Enforcement Actions

Compliance and Enforcement Actions Related to Part D Auto-Forwards: We are alarmed by CMS' report on the high volume of cases that are auto-forwarded to the IRE, resulting from failures by plan sponsors to meet the required adjudication timeframes. We strongly support CMS' intention to increase the level and severity of compliance and enforcement actions imposed on Part D sponsors that substantially fail to comply with adjudication requirements for coverage determinations and redeterminations. As noted above, we strongly encourage CMS to include publication on plan websites, on Plan Finder, and otherwise about such enforcement actions where compliance failures in this and other areas are uncovered.

Innovations in Health Plan Design: We continue to support implementation of both the MA Value-Based Insurance Design (V-BID) demonstration and the Part D Enhanced MTM Model. We urge CMS to regularly engage with multiple stakeholders—including beneficiaries and consumer advocates—as the demonstrations are implemented. As noted in our comments on the MA V-BID model, we believe that multiple stakeholders should be granted opportunities to share lessons learned, weigh in on demonstration tools, such as beneficiary notices and evaluation frameworks, and provide input on mid-course corrections or shifts in the program design.¹¹

In addition, we encourage CMS to explore creating an independent ombudsman program for the purposes of monitoring and assisting beneficiaries in all demonstration programs underway at the Center for Medicare & Medicaid Innovation (CMMI). Ombudsman programs are being successfully used in the financial alignment models for dually eligible beneficiaries as well as to monitor the Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding program.¹² These independent entities are responsible for monitoring beneficiary access to care, in addition to limiting beneficiary confusion and promoting enhanced understanding.

Section II – Part C

Guidance on the Future of Provider Directory Requirements and Best Practices: We commend CMS’ proposals to provide additional guidance and enhanced oversight of MA organization provider directories. We support CMS’ efforts to more rigorously monitor and evaluate MA provider directories and to pursue enforcement actions where non-compliance is identified. We applaud the goals identified by CMS to make provider directory requirements consistent across Medicare, Medicaid, and the Marketplaces, and we believe that MA provider directory standards can be strengthened through this effort.

As such, we strongly support CMS’ proposal to institute a requirement for MA organizations to provide—and regularly update—network information in a standardized, electronic format for eventual inclusion in a nationwide provider database. We support the provider directory data elements listed in the 2017 Advance Notice and Call Letter. In particular, we commend CMS for including elements on non-English languages spoken by the provider and disability access. We urge CMS to add (both as a best practice and for future rulemaking) an element on whether a provider is currently accepting new patients who are members of the plan.

Looking forward, we continue to believe that provider directory integration in Plan Finder would greatly enhance beneficiaries’ ability to choose among MA plans based upon the criteria most important to them. Incorporating accurate provider directories in a searchable and integrated way would significantly improve the utility of Plan Finder for MA searches and ease plan selection for people with Medicare. As such, we strongly encourage CMS to incorporate this goal in the agency’s planning as it develops future policy on this issue.

Meaningful Difference (Substantially Duplicative Plan Offerings): We continue to support CMS’ position that MA organizations with multiple plans in a service area guarantee meaningful differences between plans. We

¹¹ Medicare Rights Center, “RE: Medicare Advantage Value-Based Insurance Design (VBID) Model,” (September 2015), available at: <http://medicarerights.org/pdf/091515-ma-vbid-comments.pdf>

¹² For more information on the ombudsman programs for the Medicare-Medicaid financial alignment demonstrations, see: <https://www.cms.gov/MedicareMedicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-CoordinationOffice/FinancialAlignmentInitiative/FundingtoSupportOmbudsmanPrograms.html>; For more information on the Competitive Acquisition Ombudsman, see: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Competitive_Acquisition_Ombudsman.html

find that beneficiaries are better able to evaluate plan choices and determine their best match when they are able to clearly discern differences between plan offerings. Allowing multiple plans to be offered by the same parent company that do not meaningfully differ in terms of costs or benefits simply adds noise to the market, increases confusion, and potentially allows companies to improperly steer certain types of beneficiaries to one or another of their otherwise identical products.

Policy Updates

Tiered Cost Sharing of Medical Benefits: CMS notes that MA organizations continue to be allowed to use tiered cost sharing designs for contracted, network health care providers, "...as an incentive to encourage enrollees to seek care from providers the plan identifies based on efficiency and quality data."¹³ While we are generally supportive of CMS' aim to promote the delivery of high-quality, cost-effective care, we request clarification on the following:

- To what extent is tiered cost sharing for contracted, network providers practiced?
- What metrics do MA organizations employ to evaluate health care provider quality and efficiency?
 - How transparent are these metrics?
 - In particular, how are these metrics communicated to beneficiaries?
- How is CMS evaluating beneficiary-facing content on these tiers?
- What oversight is CMS employing to minimize the risk of adverse selection resulting from this practice?

We are particularly concerned about how these tiered networks are presented to beneficiaries. Based on our experience with preferred- and non-preferred pharmacy networks in Part D, we know that people with Medicare often find it difficult to grasp the concept of networks within networks. In the absence of strict oversight, transparent criteria for determining value, and robust beneficiary education, we would be hesitant to support attempts by CMS to further encourage tiered provider network designs among MA organizations.

We urge CMS to carefully evaluate 'preferred' networks based on size and availability, and to monitor for designs that discriminate or discourage enrollment among beneficiaries with certain conditions. It is also critical that CMS monitor how tiered networks are used within specific geographic regions in a plan's coverage area, as we are concerned that providers who treat primarily lower-income or non-native English speakers may be categorized as non-preferred.

Cost Sharing/Bundling and Facility: Like CMS, we are concerned about the transparency of cost sharing for MA enrollees, and we agree that beneficiaries should be readily able to understand their cost sharing responsibilities. We hear directly from MA enrollees facing the situation described in 2017 Advance Notice and Call Letter where a person receives a service in a facility setting that includes an additional facility fee that does not apply when the service is furnished in a physician's office and these amounts are separately billed.

As such, we support CMS' directive that MA plans "should to the extent possible include the enrollee's entire cost sharing responsibility in a single copay."¹⁴ We agree that this approach will make it easier for MA enrollees to understand and anticipate the cost sharing they will incur prior to receiving services. Accurate and predictable

¹³ 2017 Advance Notice and Call Letter at 171.

¹⁴ Id.

information about cost sharing is essential to beneficiary decision-making about plan selection and to the management of an individual's health care costs, particularly for those living on low and fixed incomes.

Alternative Payment Models (APMs): We applaud CMS' commitment to move the health care delivery system away from rewarding volume over value, and we share the agency's goals to advance value-based payments in traditional Medicare. We appreciate that CMS is collecting data from MA plans about the proportion of plan payments made to providers according to the four categories of value-based payments identified by HHS.

We strongly recommend that CMS also collect and release information on how MA plans measure "value" in each payment category. While the proportion of value-based MA payments will provide useful information, it is equally important to assess and compare how MA plans are making "value" determinations about contracted providers. Also, we continue to recommend that CMS include beneficiaries and consumer advocates in the agency's ongoing dialogue about the use of value-based payment systems in MA, specifically to assess needed messaging, education, and tools to help beneficiaries navigate a continuously evolving delivery system.

Connecting Beneficiaries to Care: We appreciate CMS' request for recommendations to increase uptake of the preventive and screening services made available to Medicare beneficiaries through the ACA. We suggest that CMS and MA plans conduct outreach to providers to assist them in identifying existing patients who are nearing Medicare eligibility as well as individuals who accessed a preventive service in the past but did not have an annual wellness visit in the previous year. Combined with direct-to-consumer educational materials from CMS and MA plans, we expect working with health care providers with whom beneficiaries have an existing relationship may increase adherence to recommended screening timelines.

Prohibition on Billing Medicare-Medicaid Enrollees for Medicare Cost-Sharing: We appreciate CMS' reminder to MA plans about prohibitions on balance billing of dually eligible Qualified Medicare Beneficiary (QMB) enrollees, and we support the agency's suggestion that MA plans take affirmative steps to educate health care providers about these prohibitions. We also support CMS' recommendation that MA plans review grievance and Complaint Tracking Module (CTM) data to identify problems related to the balance billing rules.

We encourage CMS to also remind plans of their obligation to ensure that all beneficiaries, especially full-benefit and partial-benefit dually eligible beneficiaries who are protected from balance billing, have access to an adequate provider network. Plan sponsors should be responsible for curbing the practice of in-network providers who refuse or are reluctant to see low-income Medicare beneficiaries when they cannot charge cost sharing.

Dual-Eligible Special Needs Plans: CMS expresses its ongoing interest in promoting integrated care for beneficiaries who are enrolled in both Medicare and Medicaid, and conveys a desire to continue to grant increased flexibility and other benefits to Dual-Special Needs Plans (D-SNPs) with high levels of integration outside of the Financial Alignment Initiative led by the Medicare and Medicaid Coordination Office (MMCO). We encourage CMS to continue bring lessons learned from the Financial Alignment Initiative and other related demonstrations to the broader D-SNP market.

CMS seeks comment on ways that they can further empower and engage States in the administration and review of D-SNPs. We support providing advance notice of D-SNP termination or service area changes to the relevant State agencies, so that they can coordinate communication about resulting changes to the delivery of Medicaid services. In general, we strongly support efforts to integrate and streamline communications about benefits

changes, and we encourage CMS to work with States to ensure that messages about terminating plans are comprehensive and accurate—including information about the potential effect upon all benefits, rather than piecemeal notices from different sources.

We also support establishing procedures for enhanced and concurrent review of the D-SNP Model of Care (MOC) by States and Medicare. We applaud the agency’s interest in exploring ways for States to provide specificity about their requirements for long-term care provision into the criteria for MOC review. We expect that collaboration between CMS and States to create effective review tools, together with the proposed concurrent review process by States and NCQA, would set clearer expectations about plan’s obligations in providing both Medicare and Medicaid benefits.

As CMS continues to explore ways to facilitate the integration of Medicare and Medicaid benefits by D-SNPs and improve the experience of care for dually eligible beneficiaries, we encourage the agency to consider the following recommendations:

- **Promote language access:** A particular concern is communications in languages other than English. Many D-SNP beneficiaries receive a wide range of notices in their preferred language for their Medicaid benefit because the state Medicaid agency requires it. Yet, in Medicare, these same individuals often receive notices in English without even a multi-lingual insert because Medicare rules are much more limited.

To the extent that administrative flexibility is needed to allow more translated materials, we fully support such flexibility. Moreover, we believe that D-SNP plans should be required to comply with Medicare or Medicaid language access and alternative format rules—whichever are more favorable to the beneficiary—so that beneficiaries receive consistent notifications in one language.

- **Test model notices:** We encourage CMS to develop model notices, which are then tested among consumers. Plans should be allowed and encouraged to test notices developed by, or in consultation with, CMS. In our experience, notices developed with stakeholder participation, including consumer advocates, are much stronger and clearer to beneficiaries.

Section III – Part D

Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status: While we remain concerned about CMS’ encouragement of the blanket use of prior authorization for prescription drugs that have a high likelihood of use for a non-medically-accepted indication, we appreciate the agency’s reminder to plans about the use of “grandfathering” policies, whereby prior authorization decisions are carried forward to future plan years, eliminating the need for repetitive appeals. We share CMS’ favorable outlook on the use of these policies, particularly for people with chronic conditions.

As such, we encourage CMS to take this policy further and require “grandfathering” policies. We understand that plans will need to periodically assess whether “grandfathering” remains appropriate; yet, we urge CMS to encourage retrospective drug utilization reviews as opposed to arbitrary limits in order to promote uninterrupted access to needed medications.

Medication Therapy Management: While we are strongly supportive of medication therapy management programs, we continue to share CMS’ concerns that MTM programs are not adequately serving beneficiaries.¹⁵ While it remains difficult to gauge the relative success of MTM programs, given the lower than expected enrollment and limited evidence of the program’s efficacy, we support CMS’ efforts to acknowledge and reward effective—as opposed to merely existent—MTM programs.¹⁶ As such, we support CMS’ continued efforts to develop an MTM audit protocol.¹⁷

Concerning proposals in the 2017 Advance Notice and Call Letter, we support the agency’s enhanced MTM submission and approval process, which now requires attestation. In addition, we remain supportive of CMS’ Enhanced MTM Model beginning in 2017. Though, as noted above, we continue to encourage the agency to actively involve multiple stakeholders—including beneficiaries and consumer advocates—as the Enhanced MTM demonstration is implemented by creating opportunities to weigh in on beneficiary notices, evaluation frameworks, mid-course shifts in program design, and so forth.

Improving Clinical Decision-Making for Certain Part D Coverage Determinations: The regulations for Part D coverage determinations prescribe that a plan sponsor must notify an enrollee of its decision no more than 72 hours from receipt of the request for standard requests for benefits and no more than 24 hours from receipt of the request for expedited requests for benefits. These adjudication timeframes are necessary because the majority of Part D coverage determination requests involve medications a beneficiary has not yet received, increasing the risk of adverse outcomes if access to the prescription drug is delayed.

CMS proposes to allow extensions to these timelines. In general, we share the agency’s concern that expediency may occur at the expense of sound clinical decision-making, resulting in access delays for affected enrollees who must request an appeal. Still, we have some concerns about the additional flexibility contemplated for rulemaking in the 2017 Advance Notice and Call Letter. We want to ensure that, if misapplied by plan sponsors, this exception does not become the norm. Given well-documented shortcomings in Part D sponsor compliance with existing coverage determination and appeals processes, we believe this concern is warranted.¹⁸

As such, we recommend that CMS test this flexibility through a carefully designed pilot before the agency proceeds with rulemaking. We urge that the pilot include control groups to determine how frequently plans will invoke this flexibility and how the time from presentation of prescription to access varies under the new rules and the existing system. CMS should also involve multiple stakeholders in the pilot design and make publicly available a description and evaluation of the pilot. Further, we encourage CMS to consider the following as the agency continues to develop this proposal:

¹⁵ 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. 1947.

¹⁶ Rucker, L.N., “Medicare Part D’s Medication Therapy Management: Shifting from Neutral to Drive,” (AARP Public Policy Institute: June 2012), available at: <http://www.aarp.org/health/medicare-insurance/info-06-2012/medicare-part-d-mtm-AARP-ppi-health.html>

¹⁷ 2017 Advance Notice and Call Letter at 152.

¹⁸ See: CMS, “The 2014 Part C and Part D Program Audit and Enforcement Report,” (October 2015), available at: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2014_Part_C_Part_D_Program_Audit_Annual_Report.pdf; CMS, “The 2013 Part C and Part D Program Annual Audit and Enforcement Report,” (October 2014), available at: <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2013CandDProgramAuditAnnualReport.pdf>; and CMS, “Re: Common Conditions, Improvement Strategies, and Best Practices based on 2013 Program Audit Reviews,” (August 2014), available at: <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/HPMS-Memo-Common-Conditions-Improvement-Strategies-and-Best-Practices-2013-Audits.pdf>

- Allow extensions only for stand-alone Part D plans and for MA plans where a prescription is written by an out-of-network prescriber. Given their access to enrollee medical information, we expect that MA plans should be readily able to process coverage determination requests, particularly where an in-network provider is involved, meaning extensions are not warranted;
- Pilot an alternative process by which adverse coverage determinations are automatically elevated to redetermination, alleviating burden on the beneficiary to formally request an appeal; and
- Create context-specific, model notices for Part D enrollees whose coverage determinations are delayed. Engage consumer advocates in the development process and test all notices through focus groups.

Access to Preferred Cost-Sharing Pharmacies: Like CMS, we remain concerned about beneficiary access to preferred cost sharing pharmacies, and we commend the agency for its efforts to address this issue. We agree with CMS’ decision to continue its monitoring efforts, and we are encouraged by the results reported in the 2017 Advance Notice and Call Letter about increased access to preferred cost sharing pharmacies. We continue to believe, however, that beneficiary access to these preferred cost sharing arrangements would be best supported by CMS’ prior proposal to allow any willing pharmacy to participate in offering preferred cost sharing.¹⁹

With respect to identifying outlier plans, we recommend that CMS post access data on preferred cost sharing pharmacies on Plan Finder, in addition making the information available on CMS.gov and through required marketing materials. In general, we observe that people with Medicare visit and use Plan Finder far more frequently than CMS.gov. To promote informed consumer decision-making and further incentivize plans to ensure adequate access to preferred cost sharing pharmacies, we urge CMS revisit to its existing policy and incorporate preferred cost sharing pharmacy access information on Plan Finder.

Part D Benefit Parameters for Non-Defined Standard Plans

Tiering Labeling and Composition: CMS proposes adding a “non-preferred drug” tier labeling option to the formulary design to better reflect that Part D plans may include both non-preferred generic and non-preferred brand prescription drugs on the existing “non-preferred brand” tier. Like CMS, we believe the inclusion of generic medications on the “non-preferred brand” tier leads to beneficiary confusion. As such, we generally support allowing Part D plans to use the label “non-preferred” for a blended brand/generic tier.

For that reason, we are concerned by the agency’s proposal to allow sponsors that continue with the label “non-preferred brand” to place both brand and generic prescription drugs on that tier, with the stipulation that CMS will identify “outlier” tiers that are not mostly made up of brand medications. Instead, we urge CMS to require that any plan sponsor that opts to combine brand and generic prescription drugs on the non-preferred tier must use the “non-preferred drug” label, and any plan that uses the “non-preferred brand” label must do so for a tier comprised of only brand medications.

We regularly hear from people with Medicare who struggle to understand the tiered structure of their Part D plan and varying cost sharing across tiers, leading to further difficulties with comparing and contrasting plan options during the open enrollment period. As such, we strongly encourage the use of simple and accurate labels

¹⁹ 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) pp. 1918-2073 (to be codified at 42 CFR Parts 409, 417, 422, et al.)

to describe the types of prescription drugs available on plan tiers. Labeling a tier “brand,” while also allowing the placement of generic medications on that tier does not serve this purpose.

CMS also recommends that plan sponsors use a coinsurance- rather than a copayment-based structure for combined brand/generic tiers to ensure that Part D enrollees receive an actual benefit from their coverage for generic medications. The example in the 2017 Advance Notice and Call Letter of a generic prescription drug with a retail cost of \$40 on a \$50 copayment tier is one we have heard about on our helpline. We share CMS’ concern about this circumstance.

Yet, there are notable downsides to the use of coinsurance versus copayments. We find that coinsurance-based tiers offer less predictability and often lead to confusion among beneficiaries, a trend that we regularly observe among clients on our helpline. Further, coinsurance on expensive brand medications can quickly become unaffordable for people with Medicare living on low or fixed incomes.

To better communicate expected costs for coinsurance-based tiers, we recommend that Plan Finder include coinsurance ranges in percentage and dollars in the results page, and we encourage CMS to pursue this change. It is important to note that we remained concerned about the increasing use of coinsurance by Part D plans, particularly as non-specialty tiers can utilize coinsurance rates as high as 60 percent (as written in the 2017 Advance Notice and Call Letter)—leading to potentially high cost sharing for both brand and generic medications.²⁰

We appreciate CMS’ continued interest in allowing formulary designs among Part D plans that permit plan sponsors to mitigate the rising cost of prescription drugs. Unfortunately, however, the increasing complexity of Part D formularies—including five cost sharing tiers with blended brand and generic medications, varying use of coinsurance and copayments, and the proliferation of utilization management tools across tiers—makes the Part D benefit increasingly difficult for beneficiaries to comprehend and leads to persistent challenges as people with Medicare seek to compare and contrast plan options.

While flexibility in plan design may strengthen plan sponsors’ ability to negotiate discounts with pharmaceutical manufacturers, we find it often impairs beneficiaries’ ability to understand and use their prescription drug benefits. Further, modifications in formulary design prove insufficient to fully shield people with Medicare from unaffordable cost sharing, resulting in poor adherence and other adverse consequences. We continue to observe that the affordability of prescription drugs remains a persistent challenge for older adults and people with disabilities living on low and fixed incomes, and we urge CMS to work with members of Congress to advance legislative solutions to stem the rising costs of prescription drugs.

Benefit Review: We support CMS’ continued scrutiny of plan design and evaluation of tiering structures to identify discriminatory practices. As noted above, we remain concerned that formulary robustness and affordability are declining. According to a 2014 study, the affordability of prescription drugs has actually declined for some Part D enrollees. Specifically, the study found that older adults with four or more chronic conditions observed an *increase* in the prevalence of cost-related non-adherence from 2009 to 2011, reversing previous downward trends.²¹

²⁰ 2017 Advance Notice and Call Letter at 191, Table 42.

²¹ Naci, et al. “Medication Affordability Gains Following Medicare Part D Are Eroding Among Elderly With Multiple Chronic Conditions,” *Health Affairs*, August 2014, available at: <http://content.healthaffairs.org/content/33/8/1435.abstract>

Given these trends, we continue to request that CMS carefully review Part D formulary designs and explore opportunities to lessen the burden of cost sharing on Part D enrollees. In particular, we suggest that CMS closely examine the types of medications most commonly placed on Part D plans' non-preferred brand and specialty tiers. We encourage CMS to consider ways that formulary design, such as through value-based insurance design (V-BID) principles, may be employed to increase the affordability of first-line, clinically-preferred medications. While we do not expect that formulary design modifications will alleviate cost sharing concerns for all high-cost medications, we suspect these solutions may offer targeted relief to select beneficiaries.

Additional oversight, monitoring, and research are needed to ensure that the Part D benefit remains an affordable choice for comprehensive prescription drug coverage. In addition, we urge CMS to consider making available more information on how CMS monitors for discriminatory design, by releasing information on its review process, on notable or common circumstances where potentially discriminatory practices are uncovered, and so forth. We believe this is particularly important given trends concerning the increasing use of coinsurance for high-cost medications.

With respect to the 2017 Advance Notice and Call Letter, we greatly appreciate that CMS is encouraging Part D sponsors to offer \$0 copayment or low cost sharing for vaccines. We also support CMS' use of increasingly stringent meaningful difference requirements. As described above, we continue to support the agency's commitment to ensuring that people with Medicare are able to choose among meaningfully different plans.

Specialty Tiers: In the 2017 Advance Notice and Comment Letter, CMS increases the specialty tier threshold for the first time since 2008—to \$670. We support this change, and we encourage CMS to release a detailed methodology, as it did in 2014 and 2015, on the calculation of the threshold.²² We appreciate that CMS will test the proposed increase and continue to perform additional analysis to assess whether future adjustments are needed, and we urge CMS to make any such information publicly available.

Further, we support CMS' proposal to include a link on Medicare.gov to the Medicare Drug Spending Dashboard, but we encourage CMS to consult with beneficiaries and consumer advocates about how to introduce that information without adding confusion to an already information-dense search tool.

It is important to note that we remain concerned about Part D specialty tiers in two respects. First, we continue to find 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 on the specialty tier as well as the non-preferred brand tier.

Second, we continue to urge that CMS allow tiering exceptions for prescription drugs placed on a plan's specialty tier, both as a matter of fairness and to promote affordable access to high-cost medications. We urge CMS to allow tiering exceptions for all specialty medications, or to consider limited cases where these exceptions would benefit a notable share of beneficiaries. At a minimum, we encourage CMS investigate the effects of how allowing tiering exceptions on the specialty tier. Important, unanswered questions include:

- How many prescription drugs commonly placed on specialty tiers have a therapeutic equivalent on a lower tier that would ultimately allow for a tiering exception? We understand that most prescription drugs placed

²² CMS, "Medicare Part D Specialty Tier," (April 7, 2014), available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/SpecialtyTierMethodology.pdf>; CMS, "Medicare Part D Specialty Tier," (April 7, 2015), available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/CY-2016-Specialty-Tier-Methodology.pdf>

on the specialty tier are single-source medications, suggesting that many prescription drugs lack the equivalent medication on a lower tier to permit tiering exceptions.

- How frequently are tiering exceptions requested, and with what frequency could it be expected that people with Medicare would request tiering exceptions for prescription drugs placed on the specialty tier? Our general sense is that requests for tiering exceptions are exceedingly rare. We continue to urge CMS to strengthen beneficiary and provider outreach and education on the availability of tiering exceptions. Nevertheless, the frequency of these requests is an important consideration in evaluating how an allowance for tiering exceptions on the special tier would affect both enrollees and plans.
- Given the questions above, what are the expected costs to Part D sponsors if tiering exceptions were allowed on the specialty tier? And would there be an impact on Part D plan premiums?

We believe an analysis of this kind is necessary to determine whether the long-standing prohibition on tiering exceptions on the specialty tier is warranted. Particularly if any such analysis were to reveal that allowing tiering exceptions would have a minimal effect on plan costs, then we would hope this policy would be revisited. We urge CMS to conduct research along these lines and make its analysis publicly available.

Generic Tier \$0 Copay Plans: CMS outlines several mechanisms available to plans to encourage generic medication use among Medicare beneficiaries. We strongly support CMS' suggestions to Part D plan sponsors to offer \$0 copayment generic tiers and to exempt the generic tier from a plan's deductible. First-dollar coverage for generic medications may increase generic prescription drug use over brand medications and may also increase overall medication adherence.

It is important to note, however, that beneficiary cost sharing is not the only factor in medication selection. We often hear from helpline clients whose providers did not discuss generic or lower cost options when writing a prescription. Unfortunately, many of our callers are hesitant to question their doctor's decision-making, even when their prescription drug costs are high. As such, it is essential to advance educational opportunities for health care providers about the availability and efficacy of generic medications and the option to request a tiering exception based on medical circumstances. We urge CMS to undertake, and encourage Part D sponsors to engage in, efforts to inform both prescribers and Part D enrollees about these options.

Improving Drug Utilization Review Controls in Medicare Part D: CMS describes the successes that Part D sponsors achieved in identifying and reducing opioid overuse in the Part D program since 2013. We are glad to see these results and strongly support well-designed interventions to prevent and treat overuse and addiction.

CMS' Expectations for Formulary-Level Cumulative Opioid POS Edits in CY 2017: Based on the success of a pilot conducted last year, CMS indicates that creating cumulative edits at the point of sale (POS) is feasible for Part D sponsors. According to CMS, the pilot "...demonstrated that they [plan sponsors] can effectively implement soft and hard formulary-level cumulative MED edits at POS while blocking the edit for beneficiaries with known exceptions."²³

As a result, CMS expects Part D sponsors to implement such edits in 2017 and proposes parameters for both soft edits (meaning they can be overridden by pharmacists) and hard edits (meaning that they require a coverage

²³ 2017 Advance Notice and Call Letter at 202.

determination to be overridden). While we support CMS' goal to identify and prevent potential overutilization, we are concerned about the potential for false positives, particularly among those who do not meet the exception categories identified by CMS.

We would prefer that CMS only require soft edits, which will alert the pharmacist and prescriber to a potential problem and do not risk creating barriers to access for needed medications and unduly burdening Medicare beneficiaries with the need to pursue coverage through the appeals process. Continued concerns with non-compliance and poor audit results related to Part D coverage determinations and appeals provide sufficient reason to question the use of hard edits, particularly when soft edits may serve the same aims.²⁴

While CMS' most recent summary report determined that Part D sponsors had shown improvement in overall audit scores for 2014, including notable improvements in coverage determinations, appeals, and grievances, no specifics on these improvements have been publicly released.²⁵ Further, the 2017 Advance Notice and Call Letter highlights troubling trends among Part D sponsors related to the untimely adjudication of plan-level appeals.²⁶ These concerns, coupled with CMS' favorable reporting on current efforts to identify opioid overuse, lead us to encourage the agency to revisit its recommendation to require both soft and hard edits.

Access to Medication-Assisted Treatment: We support CMS' intention to inform physicians, MA organizations, and Part D sponsors about available Medication-Assisted Treatment (MAT) for opioid addiction under Medicare. The agency also encourages Part D sponsors to avoid prior authorization that duplicates other criteria and to carefully consider prior authorization approval durations "...so as not to subject beneficiaries who are in need of these therapies to unnecessary hurdles."²⁷ We agree with this standard in this instance, and we ask CMS to urge sponsors to consider the necessity of all formulary edits using this rubric.

CMS also requests input on whether the Part D exclusion of methadone for substance abuse treatment (unlike buprenorphine, buprenorphine/naloxone and naltrexone) is a barrier to treatment. We believe that it is. As such, to the extent possible, we encourage CMS to incorporate coverage for methadone for this purpose.

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,

²⁴ See: CMS, "The 2013 Part C and Part D Program Annual Audit and Enforcement Report," (October 2014), available at: <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2013CandDProgramAuditAnnualReport.pdf>; and CMS, "Re: Common Conditions, Improvement Strategies, and Best Practices based on 2013 Program Audit Reviews," (August 2014), available at: <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/HPMS-Memo-Common-Conditions-Improvement-Strategies-and-Best-Practices-2013-Audits.pdf>

²⁵ CMS, "The 2014 Part C and Part D Program Audit and Enforcement Report," (October 2015), available at: [https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2014 Part C Part D Program Audit Annual Report.pdf](https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2014%20Part%20C%20Part%20D%20Program%20Audit%20Annual%20Report.pdf);

²⁶ 2017 Advance Notice and Call Letter at 153.

²⁷ 2017 Advance Notice and Call Letter at 205.

reduced adherence to treatment protocols, and higher than appropriate out-of-pocket health care costs for older adults, people with disabilities, and their families.²⁸

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.²⁹ 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.³⁰

Our experience, coupled with CMS' reporting on poor audit results and related sanctions,³¹ 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;
- 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).³²

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.

²⁸ 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>

²⁹ 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>

³⁰ 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>

³¹ 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.

³² 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>

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.³³

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.³⁴

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

³³ 2016 Announcement and Final Call Letter at 81.

³⁴ CMS, “2016 Point of Sale (POS) Pilot Event” Webinar held on January 21, 2016.

participant reported a 50% increase in beneficiary access (either to the prescription drug in question or a suitable formulary alternative)—clearly a potential success.³⁵ 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.³⁶ 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 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

³⁵ Id.

³⁶ 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>

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.³⁷

- 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.

Extended Days' Supply and First Fill Quantity Limits: We commend CMS' for efforts to promote transparency on plan policies concerning extended days' supply and first fill quantity limits. In addition, we share the agency's concern about the potential for excessive waste and expense in situations where a 2-3 month supply is not utilized for the first fill of a given prescription. While we appreciate CMS' call for clear information in beneficiary materials on first fill quantity limits and affected medications, we are concerned about enrollee access to this information.

We foresee confusion on the part of the beneficiaries as quantity limits change from first to second fills and extended days' supply options differ between otherwise similar medications. For this reason, we recommend that CMS require plans to provide individualized information to enrollees, such as alerting them to first fill quantity limits when receiving a relevant prescription for the first time. We also believe beneficiaries would be well served by making extended days' supply and first fill quantity limits information available on Plan Finder, and we encourage CMS to add this information.

Establishing Mail Order Protocols for Urgent Need Fills to Prevent Gaps in Therapy: We strongly support CMS' proposals to require plan sponsors to work with mail order pharmacies to develop and implement protocols to rush shipment of urgently needed medications and to provide beneficiaries with clear information about rush orders in all beneficiary materials.

³⁷ 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

Section IV – Medicare-Medicaid Plans

As Medicare-Medicaid Plans (MMPs) become increasingly available to older adults and people with disabilities, clarity of communication and sufficient oversight become increasingly important. We appreciate CMS' targeted attention to these plans and the unique needs of their enrollees.

Network Adequacy Determinations: CMS will require MMPs to resubmit their network information in September 2016 to ensure that each MMP continues to maintain a network of providers that is sufficient in number, variety, and geographic distribution to meet the needs of the enrollees in its service area. We support this requirement as we have worked with enrollees in MMPs who have received dated network information, resulting in delayed access to care. We encourage CMS to consider, when reviewing the network information, whether the listed providers who speak additional languages can accommodate persons with disabilities and are currently accepting new MMP patients.

Model of Care: CMS encourages MMPs to use off-cycle opportunities to update their Models of Care (MOC), most of which were developed before the finalization of the three-way contract. This will allow plans to ensure that their MOCs are aligned with all demonstration requirements. We support these efforts to align the MOCs.

Formulary and Supplemental Drug Files: CMS requires MMPs to submit Part D formulary and other information in a supplemental file about non-Medicare covered drugs that are covered under Medicaid program rules. While we understand the historical reason for this separation, we urge CMS to work towards the creation of integrated formulary submissions and concurrent, rather than separate, review of the Part D and Medicaid-covered drugs.

We encourage CMS to develop special procedures for prescription drugs that may be covered under Part D in some circumstances but, when they are not, are covered under the Medicaid program. CMS should ensure that there is adequate coverage and coordination between the formulary and supplemental drug file for these prescriptions. We find that these medications can cause particular access problems. Examples include prescriptions drugs for cough and cold symptoms, medicines that are frequently used for a medically accepted but not FDA-approved indication, and prescription drugs to affect weight gain.

Thank you for the opportunity to provide comment.



Joe Baker
President
Medicare Rights Center