



March 3, 2017

VIA ELECTRONIC SUBMISSION

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Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter

The Medicare Rights Center (Medicare Rights) is pleased to submit comments in response to the Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter (Advance 2018 Rate Notice and Call Letter). Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, Medicare Rights provides services and resources to nearly three million people with Medicare, family caregivers, and professionals.

The following comments are informed by our experience assisting beneficiaries, their family members, and health care professionals. For additional information, please contact Stacy Sanders, Federal Policy Director at SSanders@medicarerights.org or 202-637-0961 and Julie Carter, Federal Policy Associate at JCarter@medicarerights.org or 202-637-0962.

Attachment II. Changes in the Part C Payment Methodology for CY 2018

Section A. MA Benchmark, Quality Bonus Payments and Rebate: We support the payment methodologies outlined in the Advance 2018 Rate 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. Medicare Rights continues 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. In 2018, MA plans will be paid based entirely on the fee-for-service rate. 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 and that payments to these plans remain appropriate.

Section G. MA Employer Group Waiver Plans: In 2017, CMS finalized a proposal to waive the bidding requirements for MA Employer Group Waiver Plans (EGWPs) and to pay these plans using an alternative payment mechanism, to be phased in over a two-year period. This policy is intended to reduce administrative burdens on employer plans and to more accurately capture EGWP costs by eliminating incentives to submit bids that are higher than actual projected costs.

This change in payment methodology was supported by findings from the Medicare Payment Advisory Commission (MedPAC). According to a 2014 MedPAC report, average Medicare payments to EGWPs were 106% of Traditional Medicare costs for comparable beneficiaries.¹ Further, EGWPs tend to have healthier, lower-cost enrollees than other MA plans and face lower administrative costs related to enrollment and marketing. As such, Medicare Rights generally supports these waived bidding requirements and phased payment changes, as outlined in the Final 2017 Rate Notice and Call Letter.²

In the Advance 2018 Rate Notice and Call Letter, CMS suggests that the agency may not complete phase-in of the payment changes in 2018. MedPAC recently requested that CMS provide a rationale for delaying the phase-in, and we agree that an explanation is warranted. According to MedPAC, “EGWPs are still thriving under the new payment formula” and some plans reported the 2017 payment reduction was worth the savings in time and costs associated with the bidding process.³

At the same time, we continue to urge CMS to minimize any demonstrated disruptions in retiree health benefits resulting from the payment changes. Specifically, we encourage CMS to revisit its determination that EGWPs can no longer pay the Part B premium on behalf of their enrollees. We recognize there are administrative complexities, but we urge the agency to explore options to allow EGWPs to provide this benefit, such as by permitting employer plans to separately reimburse members for their Part B premiums.

Section H. Medicare Advantage Coding Pattern Adjustment: As in 2017, CMS proposes setting the MA coding adjustment factor to the statutory minimum. 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.”⁴ Motivation aside, these coding behaviors result in the same outcome: higher payments to MA plans than would be the case if plans coded

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

² Final 2017 Rate Notice and Call Letter, pp. 27-29.

³ MedPAC, “RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter” (February 2017), available at http://www.medpac.gov/docs/default-source/comment-letters/20170224_medpac_2018advnotice_comments.pdf?sfvrsn=0.

⁴ Advance 2017 Rate Notice and Call Letter, p. 42.

similarly to health care providers in Traditional Medicare. According to MedPAC, average risk scores grew 9% faster in MA than in traditional Medicare for comparable beneficiaries.⁵

The added cost of this “upcoding” is significant. According to a recent study, coding intensity practices could result in overpayments to MA plans totaling \$200 billion over the next decade.⁶ We continue to encourage CMS to be more assertive with its attempts to control for the impact of differential coding, such as by increasing the coding intensity adjustment. Analysis by MedPAC suggests that the statutory minimum coding adjustment will likely prove insufficient to fully offset current coding intensity trends.⁷

We also continue to encourage CMS to ensure that at-home risk assessments show services for MA enrollees that are meaningful and effective for beneficiaries’ clinical condition(s). There is a continued risk that such assessments provide a vehicle for collecting diagnoses, without guaranteeing that there is meaningful follow-up care, and attendant payment increases that do not reflect meaningful differences in risk or the provision of care.

Section K: Encounter Data as a Diagnosis Source for 2018: Medicare Rights supports CMS’ transition to the use of encounter data in calculating MA risk scores. We hope this transition will reduce coding intensity incentives that contribute to higher Medicare spending than necessary. Further, we generally believe that any payment change must be approached with caution, so as not to lead to disruptions in benefits or care for MA enrollees.

As such, we generally support CMS’ inquiry into an industry-wide adjustment for encounter-based risk scores in the short term, so long as the agency commits to both furthering encounter-based payments that diminish any inappropriate inflation of MA plan payments and to ensuring that the data underpinning these methods is appropriately vetted, accurate, and complete.

It is critically important that CMS proceed with the collection and use encounter data to improve the accuracy of the MA risk adjustment system, which may have the effect of lowering risk scores and hence reducing payments to MA plans. While we support a phased approach to the use of these methods, we do not support halting progress towards the adoption of encounter-based payments.

Attachment VI. Draft CY 2018 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

⁵ 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>.

⁶ Kronick, R., “Projected Coding Intensity In Medicare Advantage Could Increase Medicare Spending By \$200 Billion Over Ten Years” (Health Affairs: February 2017), available at <http://content.healthaffairs.org/content/36/2/320.abstract>.

⁷ 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>.

continue to encourage CMS to revisit its prior recommendation to require separate mailings of the ANOC and EOC for MA plans to bring more beneficiary attention to the ANOC. This practice would be similarly beneficial for Part D plans. The EOC is long and detailed, and many beneficiaries do not understand it, or even read it fully. By contrast, the ANOC is a shorter, more streamlined tool and, more importantly, it is time sensitive.

At the same time, improvements to the ANOC are long overdue. We often hear from MA and Part D 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, and where utilization management tools will be newly applied. Ideally, these customizations should reflect an individual's actual providers, services, and prescription drugs.

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.

Changes to Measures for 2018: We are particularly supportive of CMS' efforts to increase the accuracy of the Medicare Plan Finder (MPF) Price Accuracy measure for Part D, as we continue to hear from Part D enrollees who report notable cost-sharing differences between what was displayed on Plan Finder and what they paid at the pharmacy counter.

In particular, it is important that the measure will now account for the frequency and magnitude of difference between prescription drug event (PDE) and MPF prices when a contract's PDE prices are higher than the MPF prices. This change will better reflect the severity of price differences.

Adjusting Star Ratings for Audits and Enforcement Actions: As reflected in our November 2016 comments, we continue to support CMS' work to thoroughly evaluate how audits, civil money penalties, and sanctions impact Star Ratings.⁸ This work is important, as any disconnect between audit scores and the Star Ratings system can be a source of confusion for people with Medicare and professionals seeking to evaluate and compare health plan quality.

We strongly urge CMS to ensure that the Star Rating system does not camouflage or minimize plan behaviors that put Medicare enrollees at risk. When CMS determines that a plan's conduct poses a serious threat to the health and safety of beneficiaries, CMS should accurately signal this assessment through Star Ratings, providing beneficiaries with a clear tool that helps them fully evaluate and compare health plans.

⁸ Medicare Rights Center, "Re: Enhancements to the Star Ratings for 2018 and Beyond" (November 2016), available at <https://www.medicarerights.org/pdf/112916-comments-enhancements-star-ratings-2018.pdf>.

Of particular concern is the repeated finding of the same serious deficiencies in audit scores while Star Ratings continue to rise. To address this imbalance, it is critically important that Star Ratings incorporate audit measures and reflect audit results in meaningful ways, while CMS continues to impose significant sanctions and penalties when serious deficiencies are identified.

To solve this issue, CMS proposes to revise how civil money penalties are reflected in the Beneficiary Access and Plan Performance (BAPP) measure. But when violations are so severe that they trigger sanctions (as opposed to civil money penalties), it is not enough to merely include them as part of a measure or sub-measure. That lesser impact does not send the right signal to plans or to beneficiaries.⁹ We strongly urge the agency to revisit this policy. Specifically, we recommend that CMS reconsider more significantly weighting the BAPP measure and/or adjusting the overall and summary Star Ratings by at least one star for sanctioned plans.

Additionally, if CMS proceeds with replacing the prior policy of a reduction to the overall star rating with a reduction applied only to the BAPP measure, it is critical that Medicare beneficiaries are informed about the organizations' performance issues. We strongly support the use of a low-performing icon or other prominently displayed signal(s) of poor performance.

Data Integrity: Like CMS, we agree that data integrity is essential to safeguard the Star Ratings system. We support the reduction of a contract's star rating to one if CMS determines that the plan submitted incomplete, biased, or erroneous data. We also support increased scrutiny of plan data, particularly data related to the Medication Therapy Management (MTM) program and any plan activities that could adversely affect beneficiary access to MTM.

2018 Star Ratings Program and the Categorical Adjustment Index: We continue to be concerned by CMS' policy adjusting Star Ratings scores based on socio-economic and disability status, since it risks masking disparities in care quality. 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. Given this, we continue to urge CMS to develop a plan and timeline for phasing out this adjustment.¹⁰

2018 CMS Display Measures: We support the new and revised 2018 display measures identified by CMS. In particular, we strongly support the proposed adoption of a new display measure incorporating the Formulary Administration Analysis program. In order for the Star Ratings system to provide an accurate gauge of plan quality, it is vital for the ratings to incorporate data on whether the plan appropriately adjudicated Part D claims. This information is important for people with Medicare because it highlights their access to medications.

⁹ See "2015 Part C and Part D Program Audit and Enforcement Report" (September 2016), available at https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-andAudits/Downloads/2015_C_and_D_Program_Audit_and_Enforcement-Report.pdf.

¹⁰ See Medicare Rights Center, "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 (March 2016; pp. 5-6), available at <https://www.medicarerights.org/pdf/2017-call-letter-comments.pdf>.

Forecasting to 2019 and Beyond: We support the future changes identified by CMS for Star Ratings and Display measures. In particular, we are encouraged by the continuing focus and greater weight given to different measures of care coordination, including transitions of care, for MA plans.

Innovations in Health Plan Design: We appreciate the updates provided in the Advance 2018 Rate Notice and Call Letter on the Medicare Advantage Value-Based Insurance Design (V-BID) Model and the Part D Enhanced MTM Model underway through the Center for Medicare and Medicaid Innovation (CMMI). We applaud CMS for committing to the development of an Alternative Payment Models (APM) Beneficiary Ombudsman to monitor the beneficiary experience in new and emerging CMMI models.¹¹ Once established, we expect the APM Beneficiary Ombudsman will have an active role in tracking, monitoring, and assessing MA and Part D enrollee experiences in current and proposed health plan innovation models established through CMMI.

Section II, Part C

Plans with Low Enrollment: CMS proposes allowing Special Needs Plans (SNPs) with low enrollment in areas with insufficient competition to remain operational. We support this proposal to ensure there are plans available for people who live in rural areas or other areas with little competition.

Meaningful Difference (Substantially Duplicative Plan Offerings): CMS plans to continue requiring a meaningful difference between any two plan offerings by one MA organization, with provider networks continuing to be an ineligible characteristic to show such meaningful difference.

CMS invites interested parties to describe how differences in provider networks could constitute a meaningful difference. Should the agency advance a proposal along these lines, we strongly encourage CMS to seek public comment on any such policy to solicit more complete and targeted information, especially if tiered networks or differential cost-sharing are implicated.

Part C Cost Sharing Standards: We strongly support CMS' proposal in the Advance 2018 Rate Notice and Call Letter to bar cost-sharing for the first 20 days in a Skilled Nursing Facility (SNF).

We are concerned, however, by the rationale provided for the proposed increases in cost-sharing limits for Emergency Care/Post Stabilization Care. We understand the need to align cost-sharing with actual costs; yet, we strongly discourage implementing any such changes “as an incentive to use primary and specialty care services for routine care and avoid using the emergency room for non-emergent routine services.”¹² Many studies demonstrate that increasing a beneficiary's cost-sharing can reduce both unnecessary and necessary care, and this effect is particularly pronounced in low-income populations.¹³ This blunt tool can

¹¹ See CMS “Advancing Care Coordination through Episode Payment Models (Cardiac and Orthopedic Bundled Payment Models) Final Rule (CMS-5519-F) and Medicare ACO Track 1+ Model” (December 2016), available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-12-20.html>.

¹² Advance 2018 Rate Notice and Call Letter, p. 123.

¹³ See Gibson, T.B., et al., “Cost Sharing, Adherence, and Health Outcomes in Patients With Diabetes” (August, 2010), available at http://www.ajmc.com/journals/issue/2010/2010-08-vol16-n08/ajmc_10aug_gibson_589to600/P-2; Ku, L., “The Effect of Increased Cost-Sharing in Medicaid” (July 2005), available at <http://www.cbpp.org/research/the-effect-of-increased-cost-sharing-in-medicaid>.

have serious effects on patients seeking necessary care, and other, more tailored, strategies should be tried before relying on cost-sharing as a disincentive to seek out certain types of care.

Medicare beneficiaries, especially those with low incomes, must not be deterred from using appropriate emergency services. Alternatively, we encourage CMS and MA plans to employ positive strategies, such as care management, enhanced education, and lowered or eliminated cost-sharing, to encourage enrollees to appropriately utilize primary and specialty care.

Part C Optional Supplemental Benefits: We support CMS' continued evaluation of supplemental benefits packages to ensure that such packages are non-discriminatory and provide value to MA enrollees. Going further, we encourage CMS to review the range and type of supplemental benefits currently offered by MA plans nationwide and to make any such analysis publicly available.

We are aware that some members of Congress and health plans advocate for increased flexibility for MA plans to offer optional supplemental benefits. If applied with appropriate oversight and monitoring, this added flexibility could prove valuable, but there is little information publicly available about what MA plans currently offer.¹⁴ The current list of permissible optional supplemental benefits is fairly extensive, and evidence of whether the provision of such benefits improves care or lowers costs would be valuable to further dialogue on how these supplemental benefits might be extended to better manage chronic illness, address social determinants of health, or otherwise.¹⁵

Tiered Cost Sharing of Medical Benefits: CMS will continue to permit MA organizations to use tiered cost-sharing for their providers. While we continue to be generally supportive of improving the quality and cost effectiveness of care delivery, we would like assurances that tiered cost-sharing furthers that aim.

To that end, we seek information on the following issues:

- 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? And 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?

Clear communication with beneficiaries is critical to the success of tiered cost-sharing. Pharmacy networks within networks have presented challenges for people with Medicare Part D, and we have reservations with any efforts to spread this practice until it is clear that people with Medicare understand the rules, benefits, and choices involved in a tiered network. This requires a plan of strict oversight and transparency, in addition to proactive beneficiary outreach and education. Preferred networks likely require specialized monitoring and evaluation. In particular, their size, availability, design, and coverage

¹⁴ See, e.g., Senate Committee on Finance, "Bipartisan Chronic Care Working Group Policy Options Document" (December 2015), available at <https://www.finance.senate.gov/imo/media/doc/CCWG%20Policy%20Options%20Paper1.pdf>; McGrath, M.K. & Thorpe, K., "The Need For Additional Flexibility In Medicare Advantage" (August 29, 2016), available at <http://healthaffairs.org/blog/2016/08/29/the-need-for-additional-flexibility-in-medicare-advantage/>; Pope, C., "Enhancing Medicare Advantage, Lowering Costs for Seniors" (October 2015), available at <https://morningconsult.com/opinions/enhancing-medicare-advantage-lowering-costs-for-seniors/>.

¹⁵ Medicare Managed Care Manual, "Chapter 4 - Benefits and Beneficiary Protections," Rev. 121, pp. 32-52 (April 2016), available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf>.

areas must be carefully considered, as well as methods to guarantee providers of low-income or Limited English Proficient beneficiaries are not disadvantaged.

CMS Monitoring and Compliance Activities Regarding Encounter Data: We appreciate CMS' proposal to use performance measures related to MA encounter data submissions to guide oversight and enforcement. The progress CMS is making in this area is vital, both for purposes of risk adjustment and understanding utilization of Medicare services.

Still, we encourage CMS to more fully validate the completeness and accuracy of MA encounter data, as outlined by the Government Accountability Office (GAO) in 2014 and 2017.¹⁶ The financial stability of the Medicare program is best served by firmly anchoring any payment for services to complete, accurate data on those services. In addition, determining potential future uses of encounter data in advance will ensure that the data being collected now are the appropriate data for those purposes.

Benefit Period Clarification for PBP: In the Advance 2018 Rate Notice and Call Letter, CMS clarifies the options for MA benefit periods that may differ from the benefit periods of Original Medicare. MA plans that choose "Other" benefit periods must ensure that beneficiaries are entitled to an equal number of inpatient days as Original Medicare.

We appreciate that CMS proposes requiring that any alternate benefit period be "actuarially equivalent to Original Medicare's benefit and should be easily understood by the enrollee." Yet, we generally observe that, as a concept, benefit periods are not easily understood and often lead to confusion. We regularly field helpline calls seeking clarification about or help with benefit period misunderstandings.

Because of this experience, we seek more information about what it means to be "easily understood by the enrollee." Specifically, we request information from CMS on the strategies the agency expects to employ, or encourage MA plans to employ, to ensure that these benefit periods will be easily understood.

SNP-Specific Networks: We support further inquiry into the establishment of SNP-specific network adequacy standards. Most important, any such proposal must guarantee appropriate networks, not allow lesser standards. In addition, it is critical that SNP-specific networks do not become too targeted.

People in SNPs have various health care needs and while they may have a condition that allows them to be in a specific SNP (namely a Chronic Condition SNP or C-SNP), another condition may require health care providers unassociated with the qualifying condition. We are also concerned that certain groups of specialists would only be available in SNP-specific networks, thereby limiting necessary access to specialists for plan members in a non-SNP plan.

Decreasing Health Disparities in the Quality of Care that Vulnerable Populations Receive: We support decreasing health disparities and CMS' efforts to clarify the tools at an MA plan's disposal for such reductions, including appropriate outreach and targeted interventions. To enhance transparency, we

¹⁶ GAO Report, "CMS Should Fully Develop Plans for Encounter Data and Assess Data Quality before Use" (July 2014), available at <http://www.gao.gov/assets/670/665142.pdf>; GAO Report, "Limited Progress Made to Validate Encounter Data Used to Ensure Proper Payments" (January 2017), available at <http://www.gao.gov/assets/690/682145.pdf>.

urge CMS to provide more information about what such outreach or interventions have been or could be going forward. For example, data on how often MA plans provide language services would be valuable to help gauge efforts in this area.

Section III, Part D

Tiering Exceptions, Policy Clarifications: We greatly appreciate CMS' clarifications and reminders for plan sponsors about the guidelines for managing Part D tiering exception requests, particularly with respect to mixed tiers that include both brand-name and generic prescription drugs.

Request for Information on Tiering Exceptions: We thank CMS for soliciting input from multiple stakeholders on the Part D tiering exception process. Unaffordable prescription drugs are among the most persistent and intractable problems we hear on the Medicare Rights national helpline, and we regularly field calls from Part D enrollees who are distressed about cost-sharing for their prescription drugs.

In such cases, we typically screen callers for potential eligibility in the Part D Low-Income Subsidy (LIS/Extra Help) program and counsel on the possibility to request a tiering exception. Below we detail our experience assisting beneficiaries with the tiering exception process:

- By and large, we find that beneficiaries are altogether unaware of their right to a tiering exception, when it is appropriate to request an exception, and how to go about doing so. Most of our clients do not know what a tiering exception is until we inform them.
- From 2013 to 2017, Medicare Rights experienced a 200% increase in helpline call volume involving inquiries and counseling concerning Part D tiering and exceptions, though these represent a small number of overall counseling sessions. This includes requests concerning specialty tier medications (which represented nearly one in four cases).
- Our clients have mixed experiences engaging their health care providers in tiering exception requests, namely working with their provider to secure the necessary documentation on medical necessity. Some health care providers are more willing to assist than others.
- Similarly, our clients have mixed success engaging their Part D plans throughout the tiering exception process. A common challenge faced by our clients concerns their repeated attempts to gain clarity from the plan about what information is necessary to prove medical necessity.

Below we provide a redacted case story reflective of common scenarios involving tiering exceptions heard on the Medicare Rights national helpline:

- Ms. J was prescribed a generic medication for a sleep disorder. In the new Part D plan year, her physician submitted a request for a tiering exception because the medication was costly on Tier 4, typically one of the highest cost-sharing categories in a plan's formulary, even though it was a generic. Ms. J is unable to take the other medications in the category.

She received a denial notice from her Part D plan with no reason for the denial. Ms. J explained to our helpline counselor that it has been very difficult to obtain the criteria on which the prescription drug denial was based. She filed a grievance about the lack of information provided.

Unfortunately, even after filing a grievance, her plan's customer service representatives were still unable to provide Ms. J with clarifying information on what information was needed to support an appeal. Ms. J continued to go without because she could not afford to pay the high tier cost-sharing. As of this writing, Ms. J is awaiting further response on her appeal.

Based on these experiences, we believe that CMS and Part D plans can do more to inform beneficiaries about how and when to utilize a tiering exception and to help them more easily navigate the process. Medicare Rights recommends the following:

- **Allow tiering exceptions on the Part D specialty tier.** Tiering exceptions are currently not allowed for medications on the specialty tier—despite the fact these are among the highest cost medications, making them unaffordable for many beneficiaries with fixed incomes and limited resources.

Medicare Rights continues to urge CMS to allow tiering exceptions for prescription drugs placed on a Part D plan's specialty tier, both as a matter of fairness and to promote affordable access to high-cost medications. Alternatively, we recommend that CMS consider limited cases where these exceptions would benefit a notable share of beneficiaries or establish another mechanism for cost-sharing relief among Part D enrollees unable to afford specialty tier medications, namely those ineligible for LIS/Extra Help.

Further, we urge CMS to move swiftly to complete the agency's analysis announced in the Final 2017 Rate Notice and Call Letter on the effects of allowing tiering exceptions for specialty tier medications.¹⁷ We continue to believe further study is needed to determine whether the longstanding prohibition on tiering exceptions for specialty tier medications 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.

- **Enhance beneficiary notice about tiering exceptions at the Point of Sale (POS).** We appreciate that CMS currently requires Part D plans and pharmacies to disseminate a standard notice at the POS for circumstances involving prescription drug denials or high cost-sharing.¹⁸ As part of our standard counseling procedures, Medicare Rights asks all clients who are unable to fill a prescription about their receipt of this required notification. Year after year, the overwhelming majority of helpline callers report that they never received this notice.

As a first step, CMS should enhance oversight and enforcement of this notice requirement to ensure that Part D enrollees unable to afford needed prescription drugs are informed at the POS about tiering exceptions. Additionally, CMS should consider creating notification tailored to the tiering exception

¹⁷ Final 2017 Rate Notice and Call Letter, p. 203.

¹⁸ See "Medicare Prescription Drug Coverage and Your Rights" (Form CMS-10147), available at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/PlanNoticesAndDocuments.html>.

process and its unique rules, as opposed to disseminating a general notice that captures processes involving denials and utilization controls as well as tiering requests.

- **Create targeted denial notices for tiering exceptions.** Similarly, we appreciate CMS’ existing requirements that plans provide a standardized Part D denial notice, and we thank CMS for incorporating suggestions from Medicare Rights in its recent updates to this notice.¹⁹ Still, we continue to believe these notices would be significantly improved if they were targeted to specific circumstances. We urge CMS to develop clearer and more useful denial notices that are tailored to tiering exceptions or the basis for a denial, as opposed to relying on the current catch-all notification.
- **Work with plans to enhance notice language and communications on medical necessity.** As noted above, Part D enrollees and their health care providers are often flummoxed by what specific information a plan requires to prove medical necessity for a tiering exception. CMS should work with Part D plans to develop clear language and protocols for communicating this information, both in written notices and by plans’ customer service representatives. Additionally, CMS and Part D plans should explore opportunities to further empower and involve pharmacists in disseminating information and educating beneficiaries on the tiering exceptions process.

Additionally, CMS should provide clearer information through 1-800-MEDICARE about the tiering exceptions process and how beneficiaries may engage in it if necessary. CMS should also report data—particularly at the plan level—related to the tiering exceptions process, such as the volume of requests, approval and denial rates, and reasons for approval or denial. This will help Part D plan sponsors, pharmacies, health care providers, and beneficiary advocates better understand the process and identify additional areas for potential improvement.

Access to Preferred Cost-Sharing Pharmacies: We largely support CMS’ existing policies to identify and notify the public and Medicare beneficiaries about plans with low access to preferred pharmacies. With respect to identifying outlier plans, we again recommend that CMS post access data on preferred cost-sharing pharmacies on Plan Finder, in addition to 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 to revisit its existing policy and incorporate preferred cost-sharing pharmacy access information on Plan Finder.

Benefit Review: We support CMS’ continued scrutiny of plan design and evaluation of tiering structures to identify discriminatory practices. Nevertheless, we remain concerned that formulary robustness and affordability are declining, and we request that CMS carefully review Part D formulary designs and explore opportunities to lessen the burden of cost-sharing on Part D enrollees.

¹⁹ See “Notice of Denial of Medicare Prescription Drug Coverage” (Form CMS 10146), available at <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10146.pdf>.

In particular, we suggest that CMS closely examine the types of medications most commonly placed on Part D plans' non-preferred brand, non-preferred drug, 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.

We continue to support CMS' use of increasingly stringent meaningful difference requirements, and the agency's commitment to ensuring that people with Medicare are able to choose among meaningfully different plans. In the Advance 2018 Notice and Call Letter, we note the agency's reminder to plan sponsors about how their enhanced and basic plan offerings may be affected by meaningful difference requirements as the Part D donut hole fully closes in 2020, and we appreciate the agency's insistence that Part D sponsors plan ahead to minimize beneficiary disruption.

Specialty Tiers: CMS proposes to keep the specialty tier threshold at \$670, following from an increase in 2017. We appreciate that CMS will continue to perform additional analysis to assess whether future adjustments are needed. As noted above, we continue to find that beneficiaries living on low, fixed incomes—though not low enough to qualify for LIS/Extra Help—are going without needed medications due to high cost-sharing on the specialty tier, non-preferred brand, and non-preferred drug tier.

As noted above, we strongly urge CMS to prioritize the completion and public release of the agency's anticipated analyses on "...whether the inclusion of Part D drugs on a specialty tier adversely affects drug utilization or enrollment decisions... and the impact of tiering exceptions for specialty drugs."²⁰ With respect to tiering exceptions, we hope the following questions will be included as part of CMS' analyses:

- 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 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. The frequency of these requests is an important consideration in evaluating how an allowance for tiering exceptions on the specialty tier would affect both Part D enrollees and plans.

²⁰ Advance 2018 Rate Notice and Call Letter, p. 144.

- 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?

CMS’ Expectations for Formulary-Level Cumulative Opioid POS Edits in CY 2017: Medicare Rights commends CMS for its continued efforts to curb misuse and overutilization of opioids. Over several years, the agency rolled out a process for establishing cumulative edits at the point of sale (POS) to prevent opioid misuse. In 2017, CMS expected plan sponsors to use a combination of soft edits (meaning they can be overridden by pharmacists) and/or hard edits (meaning that they require a coverage determination to be overridden).

In 2018, CMS states it will require the use of a hard edit, at a minimum, and, at their discretion, Part D sponsors may also choose to use soft edits. Medicare Rights previously expressed concern with the requirement that plan sponsors adopt hard edits—as opposed to soft edits.²¹ Unlike hard edits, soft edits alert the pharmacist and prescriber to a potential problem and do not risk creating barriers to access for needed medications and unduly burdening beneficiaries with the coverage determination and appeals processes. 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.²²

We remain concerned about the potential for false positives, particularly among those who do not meet the exception categories identified by CMS. We understand that several State Health Insurance Assistance Programs (SHIPs) recently expressed concerns to the Medicare Ombudsman about inappropriate opioid denials. Similarly, the Medicare Rights national helpline has seen an increased number of cases in early 2017 related to unfilled opioid prescriptions at the POS. While we are still investigating these cases, this experience leads us to recommend that CMS move more slowly with the proliferation of hard edits.

Should CMS proceed with hard edit requirements in 2018, we strongly urge enhanced education and communication for all affected stakeholders, including beneficiaries, health care providers, pharmacists, SHIPs, beneficiary advocates, and Part D plans. We believe this will ensure all affected parties are adequately prepared to assist beneficiaries who may be inappropriately denied access to needed treatment.

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 are increasingly important. We continue to appreciate CMS’ targeted attention to these plans and the unique needs of their enrollees.

²¹ See Medicare Rights Center, “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” (March 2016, pp. 16-17), available at <https://www.medicarerights.org/pdf/2017-call-letter-comments.pdf>.

²² See 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>; CMS “2015 Part C and Part D Program Audit and Enforcement Report,” (September 2016), available at https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2015_C_and_D_Program_Audit_and_Enforcement-Report.pdf.

Network Adequacy Determinations: CMS will require MMPs to resubmit their network information in September 2017 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 continue to strongly support this requirement, and we urge CMS to enforce existing regulations that require MMPs to update their provider directories, as we have worked with MMP enrollees who have received dated network information, resulting in delayed access to care. We also 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.

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.

Topics Unaddressed in the Advance 2018 Rate Notice and Call Letter

Seamless Conversion: “Seamless conversion” is a practice that allows select insurers to auto-enroll an individual currently in one of their commercial or Medicaid products into an MA plan when that person becomes eligible for Medicare. In October 2016, CMS issued a temporary moratorium on its acceptance of any new seamless conversion proposals and released previously unavailable information on the practice—an action applauded by Medicare Rights.²³

Before the moratorium is lifted, we urge CMS to add stronger consumer protections and transparency to seamless conversion policies. We remain concerned that seamless conversion limits proactive decision-making by newly eligible Medicare beneficiaries, and we continue to believe that CMS should promote policies to ensure that beneficiaries can make an active and fully informed choice about the Medicare coverage option that best fits their needs.

First and foremost, we ask CMS to ensure the opportunity for public comment on any proposed or revised seamless conversion policies. Second, we urge the agency to adopt the consumer protections outlined in our September 2016 letter to CMS in any proposed policies, including: write-in confirmation, a Special

²³ CMS, “Memo: Seamless Enrollment of Individuals upon Initial Eligibility for Medicare” (October 2016), available at https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/HPMS_Memo_Seamless_Moratorium.pdf.

Enrollment Period (SEP), 1-800-MEDICARE scripts, tailored notifications and outreach for commercial insurance versus Medicaid managed care plans, and continued and enhanced transparency.²⁴

MA Provider Directories: CMS recently announced the agency’s findings from a review of 54 MA organizations, showing widespread inaccuracies in MA provider directories.²⁵ In response, the agency released additional guidance reiterating the rules MA organizations must follow for provider directories and took appropriate compliance actions. Medicare Rights applauds these actions. Directory inaccuracies can present significant challenges for enrollees—up to and including a potential lack of access to care.

As such, we encourage the agency to be vigilant in its continued inquiries, oversight, and policymaking on this issue, and we support CMS’ ongoing study in this area. We note that both MA plans and health care providers have important roles and responsibilities to facilitate directory accuracy, and CMS should actively engage both parties as the agency seeks improvements.

Additionally, we believe CMS’ recent findings are relevant to the implementation of the MA V-BID demonstration, which allows participating MA plans to lower cost-sharing for identified “high-value” network providers. In order for this effort to be successful, it is essential that beneficiaries can readily access accurate information about which providers are deemed to be high-value and which are not. As such, we encourage CMS to explore the accuracy of provider directories and related supplementary educational content for MA plans participating in the MA V-BID model.

MA Network Adequacy: In 2015, the GAO recommended changes to CMS policy to enhance oversight of MA plan network adequacy.²⁶ These changes include adding to the current adequacy criteria, improving verification and assessment of plan data, and overseeing termination notices sent to MA enrollees. While, as noted above, CMS has made efforts to address some of the deficiencies highlighted by GAO, so far such efforts appear to be primarily directed at provider directories. We urge CMS to more broadly expand its oversight and definition of network adequacy, as suggested by GAO.

Part D Appeals and 2015 POS Pilot: In the Advance 2017 Rate Notice and Call Letter, CMS reported on the agency’s pilot initiative testing multiple methods to proactively address Point of Sale (POS) rejections without requiring affected beneficiaries to request a coverage determination—an initiative supported by Medicare Rights given our longstanding observation that many beneficiaries struggle to navigate the Part D coverage determination and appeals processes.²⁷

Following the public comment period, CMS concluded, “Despite our concerns about the significant resources needed for, and potential limits of, a proactive process to resolve rejected claims, we identified multiple opportunities to address POS issues which CMS will continue to explore to develop best

²⁴ Medicare Rights Center, “Letter to CMS Acting Administrator Andy Slavitt” (September 2016), available at <https://medicarerights.org/pdf/cms-letter-seamless-conversion-093016.pdf>.

²⁵ CMS, “Online Provider Directory Review Report” (January 2017), available at https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Final_01-13-17.pdf.

²⁶ GAO, “Medicare Advantage: Actions Needed to Enhance CMS Oversight of Provider Network Adequacy” (August 2015), available at <http://www.gao.gov/assets/680/672236.pdf>.

²⁷ See Medicare Rights Center, “Letter to President Trump on Administrative Priorities” (December 2016), available at <https://medicarerights.org/pdf/transition-ltr-trump-121316.pdf>; Medicare Rights Center, “Letter to MedPAC” (March 2016), available at <https://www.medicarerights.org/pdf/medicare-rights-medpac-ltr-partd-031716.pdf>.

practices and potential future policy changes...²⁸ We request an update from the agency on these identified next steps.

Part D Transition Supplies When an Exception Expires: We ask CMS to address prescription drug protections for individuals who lose prescription drug access because an exception is expiring. Current rules provide that beneficiaries with an expiring exception have the right to a one-time transition fill.²⁹ CMS, however, overrode that directive with an August 2016 memorandum that “clarified” that the agency does “not expect Part D sponsors to include expiring formulary exceptions in their transition policies.” The reason for the reversal was plan readiness, specifically that “plans will need to make significant system changes to implement this policy, particularly with respect to exceptions expiring mid-year.”

We recognize the need to allow Part D sponsors time to make systems changes. Nevertheless, we urge CMS to set a firm start date for this transition requirement and to use the Final 2018 Rate Notice and Call Letter or other memorandum to advise plans that the requirement will become operative at the beginning of the 2018 plan year. The requirement to apply transition rules to expiring exceptions is an important consumer protection.

Inappropriate Billing of Qualified Medicare Beneficiaries (QMBs): In the Final 2017 Rate Notice and Call Letter, CMS reminded MA organizations of their obligation to prevent inappropriate billing by plan providers of members that are dually eligible for Medicare and Medicaid, specifically for QMBs.³⁰ We believe this significantly raised the visibility of QMB billing protections among MA plans and plan providers, and we thank CMS for that and for the many other steps the agency is taking to reduce inappropriate billing.

We have continuing concerns, however, about whether MA plans have put systems in place to allow MA providers to verify dual or QMB status among their patients, either through electronic systems or through identification on plan member cards. We believe challenges remain in these areas, and we ask CMS to explore this issue further.

Access to Durable Medical Equipment (DME) for Dually Eligible Beneficiaries: CMS recently issued guidance to state Medicaid agencies clarifying agency policy regarding DME access for individuals enrolled in both Medicare and Medicaid.³¹ The guidance addressed three areas of concern: Medicaid prior authorization for DME without a prior Medicare denial; proper application of Medicaid criteria when providing DME; and Medicare prior authorization.

We are pleased that CMS responded to the concerns of Medicare Rights and others by issuing this guidance, and we urge the agency to continue to work with state Medicaid agencies to ensure that

²⁸ Final 2017 Rate Notice and Call Letter, p. 219.

²⁹ CMS, “Section 30.4 of Chapter 6 of the Prescription Drug Benefit Manual,” (Last updated January 2016), available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

³⁰ Final 2017 Rate Notice and Call Letter, pp 181-183.

³¹ CMS, CMCS Informational Bulletin, “Strategies to Support Dual Eligible Beneficiaries’ Access to Durable Medical Equipment, Prosthetics, Orthotics, and Supplies,” (January 2017), available at: <https://www.medicaid.gov/federal-policy-guidance/downloads/cib011317.pdf>.

necessary changes in state practice are implemented.³² We also encourage CMS to create opportunities for flexibility in financial-alignment demonstrations and other innovation models that would allow states to test further alignment of Medicare and Medicaid in an effort to improve DME access for individuals enrolled in both programs.

Thank you for the opportunity to provide comment.

A handwritten signature in black ink, appearing to read "Joe Baker". The signature is fluid and cursive, with a large loop at the end of the last name.

Joe Baker
President
Medicare Rights Center

³² Advocate letter, "Re: CMS-1651-P..." (August 2016), available at: <http://www.medicareadvocacy.org/sign-on-letter-access-to-care-issues-for-durable-medical-equipment/>.