



March 5, 2018

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2017-0163
Baltimore, MD 21244-8016

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 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) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Call Letter (Advance 2019 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 Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Casey Schwarz, Senior Counsel for Education & Federal Policy at CSchwarz@medicarerights.org or 212-204-6271.

Attachment II. Changes in the Part C Payment Methodology for CY 2019

Section A. MA Benchmark, Quality Bonus Payments and Rebate: We support the payment methodologies outlined in this section. 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's proposed payment rates are reflective of these policies, and we support their implementation. In 2019, MA plans will be paid based entirely on the local 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

We continue to urge CMS to minimize any demonstrated disruptions in retiree health benefits resulting from these necessary 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 would be administrative complexities under this approach, 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 K. Medicare Advantage Coding Pattern Adjustment: As in 2018, 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 has previously attributed 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

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

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

revenue.”³ 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 serving patients enrolled in Traditional Medicare. According to MedPAC, average risk scores grew 9% faster in MA than in traditional Medicare for comparable beneficiaries.⁴

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.⁵ 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, including in the report cited in the Advance Notice which contains an alternative methodology,⁶ 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 effectively treat beneficiaries’ clinical condition(s). There is a continued risk that such assessments provide a vehicle for simply collecting diagnoses to increase plans’ payments, without providing any meaningful follow-up care. We urge CMS to continue to carefully monitor plans’ use of at-home risk assessments.

Attachment VI. Draft CY 2018 Call Letter

Section I, Parts C & 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 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

³ Advance 2017 Rate Notice and Call Letter, p. 42.

⁴ MedPAC, “Medicare Advantage: Status Report” (December 10, 2015), <http://medpac.gov/documents/december-2015-meeting-presentation-the-medicare-advantage-program-status-report.pdf?sfvrsn=0>.

⁵ Richard Kronick, “Projected Coding Intensity In Medicare Advantage Could Increase Medicare Spending By \$200 Billion Over Ten Years,” Health Affairs (February 2017), <http://content.healthaffairs.org/content/36/2/320.abstract>.

⁶ Advance 2017 Rate Notice and Call Letter, p. 35.

⁷ See MedPAC, “Report to the Congress: Medicare Payment Policy” (March 2015), http://medpac.gov/documents/reports/mar2015_entirereport_revised.pdf?sfvrsn=0; Andy Johnson, “Medicare Advantage Coding Intensity and Health Risk Assessments,” MedPAC (October 2015), <http://medpac.gov/docs/default-source/meeting-materials/october-2015-meeting-presentation-medicare-advantage-coding-intensity-and-health-risk-assessments-.pdf?sfvrsn=0>.

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's 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 2019:

MPF Price Accuracy (Part D): We support CMS's 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.

Removal of Measures from Star Ratings:

Beneficiary Access and Performance Problems (BAPP) (Part C & D). Medicare Rights strongly opposes the removal of the BAPP measure. As reflected in our previous comments, we continue to support CMS's work to thoroughly evaluate how audits, civil monetary 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. Moreover, these measures provide a very strong incentive for plans to focus on their operations to best serve their members.

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.

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

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

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.

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 removal of the BAPP measure, it is critical that Medicare beneficiaries are better informed in other ways 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 1 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's 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.⁹

2019 CMS Display Measures: We support the new and revised 2019 display measures identified by CMS.

Plan Makes Timely Decisions about Appeals: In particular, we support the proposal to include cases dismissed/withdrawn by the IRE into this measure. Doing so would significantly improve the accuracy of this measure. Proper and timely handling of appeals by plans is a core consumer protection. It is important that the measure be as accurate as possible.

Changes to Existing Display Measures: Hospitalizations for Potentially Preventable Complications (Part C)

We support including observation stays in this measure and agree with CMS that observation stays, like other hospital stays, can represent a failure of care coordination to prevent serious complications.

Changes to Existing Display Measures:

⁹ 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," pp. 5-6 (March 2016), <https://www.medicarerights.org/pdf/2017-call-letter-comments.pdf>.

Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D)

We suggest that this measure exclude individuals in palliative care or at end of life, not just those with cancer on in hospice. The situation of these individuals is equivalent to those in hospice or with cancer and it is important that measures do not incentivize denying them appropriate and needed pain relief.

Plan Finder Civil Money Penalty (CMP Icon) or Other Type of Notice

We strongly support the proposal of CMS to include an icon or other notice on the Plan Finder to alert beneficiaries when a sponsoring organization has received a civil monetary penalty (CMP). It is important that the icon or flag appear with each plan offered by the penalized sponsoring organization along with a link to the letter of enforcement action. As with suspensions of enrollment, plans should also be required to prominently include a link to the notice on their websites.

We appreciate that CMS responded to advocate concerns and required these disclosures for plans with enrollment suspensions. The same issues of transparency and beneficiary empowerment arise with respect to civil monetary penalties.

We also note that CMS proposes “regular updates” throughout the year. We strongly endorse an approach that updates enforcement actions in real time rather than the current practice of bunching releases of CMPs in February after the annual Open Enrollment Period has ended. Beneficiaries are asked to make market-based enrollment decisions during the OEP and, for those with Special Enrollment Periods, throughout the year. They need full transparency so that they know all the available information about a plan’s performance, and they need it in time to make informed decisions. We acknowledge that not every plan sponsor is audited every year and that some monetary penalties are relatively small, but these facts do not override the right of beneficiaries to have timely access and to make their own judgments in evaluating information that is undeniably relevant to health care choices.

Further, we ask that CMS issue press releases both for suspension of enrollment actions and civil monetary penalties. It is standard procedure for the HHS Office of Civil Rights to issue press releases when a penalty has been issued or a settlement has been agreed to, even without monetary penalty.¹⁰ Press releases serve the dual purpose of alerting beneficiaries to important information and telling the public more broadly about how well plans are serving Medicare beneficiaries.

Enforcement Actions for Provider Directories Inaccurate provider directories can mislead beneficiaries when choosing plans and can impede or delay their access to needed providers once they are enrolled. We strongly support vigorous enforcement of directory accuracy requirements.

¹⁰ See “OCR News Releases & Bulletins” (last visited March 5, 2018), www.hhs.gov/ocr/newsroom/index.html.

Innovations in Health Plan Design: We note that the Bipartisan Budget Act (BBA) of 2018 extended the V-BID model nationwide. As CMS updates the MA V-BID, we ask CMS to concentrate on expansion of the V-BID demonstration rather than on simultaneously allowing benefit flexibility outside of the demonstration. One of our many concerns is that introducing Medicare Advantage uniform flexibility while the V-BID demonstration is still in its early stages will encourage plans to forego participation in the V-BID demonstration, thus lessening the opportunities to learn from the demonstration. For more information on this and following issues, see our comments on the Medicare Advantage Uniformity Flexibility portion of the proposed Part C and D regulations.¹¹

We are also concerned that different modes of flexibility and innovation being tested and implemented simultaneously will cause significant beneficiary confusion and make the already challenging process of plan selection even more difficult.

Meaningful Difference (Substantially Duplicative Plan Offerings): We reiterate our strong objections to the proposal to eliminate the meaningful difference standard, a proposal which would only increase beneficiary confusion and impede reasoned choice among health coverage options. As discussed more fully in our comments to the proposed changes in the Part C and D regulations, we propose that, if CMS believes that there are problems with the current meaningful difference standard, the appropriate approach is to test revisions to the standard rather than abandoning it altogether.¹² Consumer research has shown that beneficiaries already are challenged in making choices among plans, and that their confusion often leads to inertia.¹³ Opening the door to additional plan choices without any requirement for meaningful differences among sponsor offerings exacerbates the problem and removes an important beneficiary protection. If, however, CMS should decide to go forward with this proposal, we believe it is very important that there be stakeholder input into the instructions to plans. The details of CMS's proposal will matter a great deal. We have serious concerns that CMS is planning to fast-track this significant change into the 2019 bid cycle without the opportunity for stakeholders to review or comment on its instructions to plans or other details.

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?

¹¹ See Medicare Rights Center, "Re: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program" (C & D Comments) (January 16, 2018), <https://www.medicarerights.org/pdf/Medicare-Rights-Center-C-D-Comments-CMS-4182-P.PDF>.

¹² See C & D Comments.

¹³ 82 Fed. Reg. at 56363.

- What metrics do MA organizations employ to evaluate health care provider quality and efficiency?
- To what degree of statistical confidence should quality and efficiency measure ratings be established (e.g., 95%)?
- 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 areas must be carefully considered, as well as methods to guarantee providers of low-income or Limited English Proficient beneficiaries are not disadvantaged.

Health Related Supplemental Benefits: We are hopeful that the broader definition of health related supplemental benefits proposed in the Call Letter will help to appropriately meet member needs and prevent avoidable injury or illness. We believe that, although the 2018 BBA eliminates the requirement that all supplemental benefits be primarily health related, the proposed changes still have the potential to be important and valuable. They cover any plan member, not just those who meet the definition of a chronically ill enrollee. We expect that, for example, there are many frail plan members who would benefit greatly from fall prevention devices but who do not otherwise require intensive care coordination—a need that is part of the chronically ill enrollee definition. Further, the 2018 BBA provisions do not take effect until 2020. The changes proposed in the Call Letter will give CMS and plans a year in which to start an expansion of supplemental benefits before the additional provisions of the BBA become operative.

While we are supportive of the proposed changes, we ask CMS to closely monitor their implementation to determine the extent to which the benefits are actually offered and utilized and to ensure that implementation is not directly or indirectly discriminatory. Tracking of benefits and outcomes also will allow CMS to evaluate the efficacy of particular supplemental benefits.

The twin issues of appropriate marketing restrictions and adequate beneficiary education on the availability of the benefit need to be carefully addressed. We ask CMS to involve stakeholders in working out those details. Beneficiaries also need full appeal rights for all denials of supplemental benefits.

Further, we note that the rationale for giving MA plan members access to items and services that diminish the impact of health conditions and reduce avoidable utilization is equally compelling for all Medicare beneficiaries, not just those who enroll in Medicare Advantage plans. We ask that CMS work to maintain an even playing field between Traditional Medicare and Medicare Advantage to ensure that effective interventions are equally available to all beneficiaries without regard to how they choose to receive their benefit.

Medicare Advantage (MA) Uniformity Flexibility: We reiterate our belief that flexibility is best tested in the V-BID model and that CMS should not simultaneously introduce it outside of the V-BID model.¹⁴ The provisions of the 2018 BBA extending the V-BID model nationally reinforce these concerns. With a national V-BID demonstration, plans in every market will have the opportunity to participate. The V-BID model includes consumer protections and evaluation appropriate to a demonstration. We ask that CMS use this demonstration as the vehicle to test uniformity flexibility and urge the agency to not dilute the demonstration by simultaneously offering general flexibility to all plans.

SNP-Specific Networks: We support further research 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. While they may have a condition that allows them to be in a specific SNP (namely a Chronic Condition SNP or C-SNP), they may also have another condition that requires 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.

Improving Beneficiary Communications and Reducing Burden for Integrated D-SNPs

Integrated Model Materials: We appreciate and support the efforts of CMS to create better and more integrated models of the summary of benefits, the ANOC, and provider and pharmacy directories. In designing model documents, we ask that CMS:

- Use plain language and a reading level no higher than sixth grade;
- Consumer test all documents;
- Use the translation standards that promote the greatest access. As was done in the Memorandums of Understanding (MOUs) in the financial alignment demonstration, where Medicare and Medicaid standards for translation and alternate formats differ, apply the standard providing the greatest access to individuals with disabilities or limited English proficiency.¹⁵ Dual eligibles who are accustomed to receiving communications

¹⁴ See C & D Comments.

¹⁵ See, e.g., “Memorandum of Understanding (MOU) Between The Centers for Medicare & Medicaid Services (CMS) and The State of California Regarding a Federal-State Partnership to Test a Capitated Financial Alignment Model for Medicare-Medicaid

about their Medicaid benefits in a language or format they can understand should not have to face the challenge of receiving information from their D-SNP that they cannot understand or use;

- Tailor the notices to the individual’s circumstances and include only information directly relevant to the purpose of the notice.

We also ask that CMS continue to work to improve other dual eligible-specific notices beyond those listed in the Call Letter and, more generally, to tailor all its notices to the specific circumstances of the beneficiary. For example, notices sent to those who are already enrolled in the Low Income Subsidy program should not say “you may qualify for Extra Help.”

We recognize that creating clear notices to explain complicated programs presents challenges and would be pleased to work with CMS on this ongoing effort.

Parts A and B Cost Sharing for Individuals Enrolled in the Qualified Medicare Beneficiary (QMB) Program: We appreciate that CMS continues its efforts to obtain full plan compliance with requirements to protect QMBs from improper billing. We also particularly thank CMS for the steps it has taken to make identification of QMBs easier for providers through the HIPAA Eligibility Transaction System (HETS).

The reports we hear from on-the-ground advocates indicate that CMS’s efforts have brought broader understanding of QMB protections and more responsiveness by plans when problems arise. The situation is improving, but challenges persist. We continue to receive reports about plan providers who do not understand the protections or are unwilling to honor them, and of plan representatives who do not understand or fulfill their obligations to protect members. Thus, we believe that CMS’s continued emphasis in this Call Letter on plan obligations to educate providers and to give them the tools to identify QMBs is fully warranted. Further, we ask that CMS monitor Complaint Tracking Module (CTM) entries to identify plans and plan sponsors that have repeated complaints in order to focus education and enforcement.

CMS Monitoring and Compliance Activities Regarding Encounter Data: We appreciate CMS’s 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

Enrollees,” p. 16 (last visited March 1, 2018), [cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/CAMOU.pdf](https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/CAMOU.pdf).

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

uses of encounter data in advance will ensure that the data being collected now are the appropriate data for those purposes.

Expanding OTC program: CMS proposes to allow PDPs: “*to include additional OTC products such as dietary supplements and cough medicines*,” without the requirement that either product offset the use of a Part D drug.”¹⁷ CMS should not adopt the proposal as it applies to dietary supplements. In fact, CMS should not sanction (and instead should explicitly prohibit) any efforts by PDPs to provide coverage for dietary supplements. The proposal is contrary to the Part D provisions in the Social Security Act. Dietary supplements are not equivalent to, and cannot be substituted for, prescription drugs; they cannot be used to treat, prevent, cure, or mitigate disease; and there is no requirement that dietary supplement manufacturers demonstrate that they are safe or effective, or even labeled appropriately before the products are marketed. Thus, if CMS were to treat dietary supplements as coverable under Part D, it would risk plans causing harm, rather than providing treatment, to Medicare beneficiaries.

Benefit Review: We support CMS’s 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.

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 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.

Tier Composition: In discussing tiering structures, CMS states that the agency continues to believe that a coinsurance structure is the preferable cost-sharing structure for the non-preferred drug tier. From the beneficiary point of view, we question the value to the beneficiary of a coinsurance structure for any tier. While a coinsurance structure might support reasoned plan selection if drug prices were predictable and constant, the unfortunate fact is that they are not. Plan Finder listing of drug prices can change as frequently as every two weeks and sometimes

¹⁷ Advance 2019 Rate Notice and Call Letter, p. 189.

those changes are dramatic. Moreover, the relative price of a drug in their plan versus other plans can also change significantly. Thus, with a coinsurance structure, beneficiaries have no way to predict their payment liability when choosing a plan or to predict whether the plan they have chosen will continue to be the most appropriate for their needs over the course of the plan year. When beneficiaries can compare plans with set co-payments, they are much better able to make informed market-based choices and budget for their health care needs.

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 analyses 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, non-preferred brand, and non-preferred drug tiers.

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.”¹⁸ With respect to tiering exceptions, we hope the following questions will be included as part of CMS’s 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.
- 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?

Part D Opioid Overutilization Policy: We appreciate the important goals in this policy. We ask, however, that CMS extend its exceptions to include beneficiaries who are at end of life but not enrolled in hospice and those in palliative care. The hospice and cancer exclusions are inadequate to address the urgent and appropriate needs of other beneficiaries in similar circumstances.

¹⁸ Advance 2018 Rate Notice and Call Letter, p. 144.

Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users: We strongly concur with CMS guidance that CMS expects Part D sponsors to “only rely on prescriber attestation that the higher MME is medically necessary to approve dosing that is higher than the hard edit when a coverage determination is requested.”¹⁹ We also endorse the CMS statement that coverage determinations seeking exceptions to the MME edit should be routinely treated as meeting the criteria for expedited review. It is important that beneficiaries appropriately needing pain management regimens can access needed medications without delay or interruptions.

More generally, we also ask that CMS emphasize to plans, providers, and participating pharmacies the importance of conducting opioid overuse prevention activities in a manner that respects beneficiaries. If beneficiaries believe they are stigmatized or become fearful of interactions with providers, the results will not serve their often complex health needs.

LIS Enrollee Cost Sharing for Out-of-Network Part D Drugs

We thank CMS for using the Call Letter to remind plans that LIS enrollees must be reimbursed the entire amount of an approved out-of-network claim minus their applicable LIS cost-sharing amount, and to remind plans further of the importance of timely reimbursements of those claims. Advocates working with beneficiaries have reported reimbursement issues when beneficiaries receive needed Part D medications from an out-of-network hospital pharmacy during an outpatient procedure, or when they had an emergency room visit or were in a hospital in observation status. The reminder and clarification in the Call Letter are most helpful. We also ask that, during the next updates to the Prescription Drug Manual, CMS provide cross-references to further clarify its policy. Specifically, we suggest that, at Chapter 5 at 60.1, CMS add a statement along the following lines: “Reminder: For LIS beneficiaries, the plan sponsor must compare the amount due from a non-LIS beneficiary under this section to the maximum cost sharing and deductible amounts due from a low-income subsidy eligible beneficiary and charge the LIS beneficiary the lesser of the two amounts. See Chapter 13 at 60.4.4 ” We also proposed that at Chapter 13 at 60.4.4, CMS add a note stating: “The requirement that the beneficiary be charged the lesser of the two amounts applies in all cases, including the calculation of reimbursements for out-of-network pharmacy payments as discussed in Chapter 5 at 60.1.” We also ask that CMS consider providing scripts and training to 1-800-MEDICARE staff on the issue.

Timely Updates to LIS Status Based on Best Available Evidence

We appreciate the admonition to plans to ensure that the Best Available Evidence (BAE) policy is implemented correctly and quickly. We continue to hear of cases where beneficiaries or their advocates have trouble finding plan staff who are familiar with BAE. At least some plans appear not to have particular staff designated to handle BAE issues, or they have not sufficiently educated other staff to spot and refer these issues. We recommend that CMS encourage all plans

¹⁹ Advance 2019 Rate Notice and Call Letter, p. 211.

to designate such individuals and ensure that their call centers have that information available. There continue to be problems in getting quick resolution once BAE information has been submitted. An additional longstanding concern is ensuring that pharmacy staff are aware of the BAE process. Pharmacy staff turnover is a significant challenge in maintaining the needed knowledge at the point-of-sale. We ask that CMS also reiterate to plan sponsors their obligation to be part of ongoing education of their in-network pharmacies on BAE.

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's targeted attention to these plans and the unique needs of their enrollees.

Network Adequacy Determinations: CMS will require MMPs to submit their network information regularly 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 prescription 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

MA Provider Directories: CMS recently announced the agency's findings from a review of 54 MA organizations, showing widespread inaccuracies in MA provider directories.²⁰ In response,

²⁰ CMS, "Online Provider Directory Review Report" (January 2017), https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Final_01-13-17.pdf.

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’s 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’s recent findings are relevant to the implementation of the MA V-BID demonstration, which allows participating MA plans to offer 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.²¹ 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.

Thank you for the opportunity to provide comment.

²¹ GAO, “Medicare Advantage: Actions Needed to Enhance CMS Oversight of Provider Network Adequacy” (August 2015), <http://www.gao.gov/assets/680/672236.pdf>.