



Getting Medicare right

March 1, 2019

VIA ELECTRONIC SUBMISSION

Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: 2018-0154
Baltimore, MD 21244-8016

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 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) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Call Letter (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 or 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 2020

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's (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 to ensuring efficient spending of taxpayer dollars.

CMS's proposed payment rates are reflective of these policies, and we support their implementation. In 2020, 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 between MA options and benefit from continued stability in the MA plan landscape. 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 F. 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 support CMS’s proposal to permit MA EGWPs to buy down Part B premiums for their enrollees using a portion of the Part C payment.

Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2020

Section A. Annual Percentage Increase in Average Expenditures for Part D Drugs per Eligible Beneficiary (API)

Annual Percentage Increase for Out-of-Pocket Threshold: Part D Out-of-Pocket (OOP) “Cliff”: Unlike past years, the Part D OOP threshold will increase significantly—by almost \$1,400 from 2019 to 2020. The phenomenon is often referred to as the “OOP cliff.” We are very concerned about the impact on beneficiaries who may linger in the coverage gap phase longer, including those with significant chronic health needs. Given the OOP costs they would face, we are concerned this could drive therapy abandonment. With the reality of this climb in the OOP threshold upon us, we hope that CMS can work with Congress to determine an appropriate solution, including making permanent the ACA provision that limits the growth in beneficiary OOP spending, and we remain supportive of this fix.³

Attachment VI:

Section I: Parts C & D

Annual Calendar: As in prior years, CMS indicates that MA and Part D plans should disseminate the Annual Notice of Change (ANOC) by September 30th. 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.

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.

³ Lower Out-of-Pocket Costs for Seniors Act (H.R. 6563), Introduced July 26, 2018, <https://www.congress.gov/bill/115th-congress/house-bill/6563?s=9&r=4>

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.

Enhancements to the 2020 Star Ratings and Future Measurement Concepts

Measure Updates for 2020 Star Ratings

2020 Star Ratings Program and the Categorical Adjustment Index: We continue to be concerned by CMS's policy adjusting Star Ratings scores based on socioeconomic 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.⁴

We oppose expanding quality measure stratification. Risk-adjustment in payment, rather than in quality assessment, better addresses the increased challenges related to serving higher needs individuals and individuals at risk because of social determinants of health. We strongly urge CMS to avoid creating disparate expectations of plan performance that would allow higher quality scores for more poorly performing plans simply because they serve lower income individuals.

To the extent that CMS does expand candidate measures for risk-adjustment of quality scores based on socioeconomic or other status, the stated exclusions—where a measure is already adjusted for socioeconomic status, where the measure evaluates plan- or provider-performance rather than beneficiary action, measures scheduled for revision, and measures specific to special needs plans (SNPs)—are an important start.⁵ We encourage CMS to broadly define and identify measures where the focus of the measurement is a plan- or provider-level issue. For example, in the listed candidate measure set for 2020, we encourage CMS to consider whether the following measures focus measurement on a beneficiary-level issue: Medication Reconciliation Post Discharge; Plan All-Cause Readmissions; Adult BMI Assessment; Osteoporosis Management in Women who had a Fracture; and Statin Use in Persons with Diabetes.⁶

We also urge CMS to retain the criteria of within-contract measure disparities. Though even within-contract differences in measure results risk masking disparities in the quality of care provided to low-income subsidy or dual eligible (LIS/DE) individuals within the plan, they at least rule out instances where CMS adjustments would hide broadly low performance simply because a high proportion of plan enrollees are LIS/DE.

2020 Display Measures

Transitions of Care: We support CMS's efforts to better evaluate a plan's success at effectively transitioning care from a clinical setting to the home, and the development of this measure.

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

⁴ 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.medicarights.org/pdf/2017-call-letter-comments.pdf>.

⁵ Call letter at 112-114.

⁶ *Id.* at 114

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.

Problems Getting Information and Help from the Plan and Problems with Prescription Drug Benefits and Coverage Disenrollment Reasons Survey Composite Measure (Part D): We support this measure, and CMS's inclusion of this information in the Medicare Plan Finder "drill down."⁷ This will allow consumers to access this needed information in a place where they are already looking as they make their enrollment decisions.

Potential Changes to Existing Star Ratings and Display Measures:

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 or 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.

Potential New Measure Concepts

Physician/Plan Interactions (Part C & D): We strongly support the development and implementation of a measure related to plan coverage and payment decisions, claims processing issues, and administrative issues between providers and plans that impact beneficiary access to care and coverage.

Patient-Reported Outcome Measures (Part C): We agree with CMS that "patient engagement is key to achieving high quality care,"⁸ and strongly believe that assessments that reflect outcomes from the perspective of the patient are essential to understanding quality as experienced by the patient. Individual variance in goals, expectations, and subjective experience are necessary to evaluate the success and quality of care and treatment. We strongly support the development and use of new and targeted patient-reported outcome measures, and are supportive of development in the area of non-opioid therapies for addressing chronic pain as contemplated by The National Committee for Quality Assurance (NCQA).⁹

Removal of Measures from the 2022 Star Ratings

Appeals Auto-Forwarded (Part D), Appeals Upheld (Part D): CMS states that these two appeals measures—using the data from the Independent Review Entity (IRE) to determine how effective sponsors are in processing coverage determinations and redeterminations—are not statistically reliable. CMS is requesting stakeholder comment on if these measures should still be display measures or if they should be retired completely. While we appreciate CMS gauging MA and Part D plan quality via statistically reliable measures, we believe strongly that there should be a mechanism to rate the effectiveness of processing determinations and redeterminations. The current appeals process is already far too opaque, so limiting information even further is a disservice to beneficiaries.

In addition, CMS audits continually show serious problems with the appeals and exceptions processes in Part D plans,¹⁰ so it is critical for transparency and oversight that there be adequate measures evaluating plan performance in adjudicating appeals and exceptions. Therefore, we recommend that CMS maintain these measures on the display page so that beneficiaries may still view plan performance in this important area. Additionally, we urge CMS to partner with quality organizations to determine the most appropriate measures to evaluate plan effectiveness regarding the appeals process.

⁷ Call Letter at 131.

⁸ Call Letter at 139

⁹ *Id.*

¹⁰ "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials" Office of the Inspector General. <https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf>

Innovations in Health Plan Design

Value-Based Insurance Design (VBID) Model Test: We support the expansion of the VBID Model Test, but urge CMS to develop additional beneficiary educational materials and resources, including the establishment of an ombudsman program to serve all beneficiaries included in Center for Medicare & Medicaid Innovation (CMMI) models as well as other model testing. Such a program could answer enrollee questions and also serve as a monitor to identify problems and issues quickly across the demonstrations.

Part C Optional Supplemental Benefits: We support CMS’s review of bid submissions to make sure that enrollees electing supplemental benefits are receiving reasonable value. Conducting this review at the MA contract level will help ensure that the bid and benefits do not discriminate against enrollees with specific or high-cost health needs. This review is important, especially in light of the expanded flexibilities plans have to offer a broader range of supplemental benefits.

Medicare-covered Opioid Treatment Program Services Beginning in CY 2020: We support CMS’s implementation of the requirements in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act¹¹ (SUPPORT PC Act) for Medicare to cover opioid use disorder treatments furnished by Opioid Treatment Programs (OTPs) in 2020.

Potential Changes To MOOP and Cost Sharing Standards for CY 2021: While we appreciate CMS’s belief that implementing more than two levels of MOOP and cost sharing limits would “encourage plan offerings with lower MOOP limits and result in more favorable benefit designs for beneficiaries,”¹² we do not know why this intermediate offering might not have the opposite effect and drive sponsors that currently offer plans with the voluntary MOOP to elect the middle option. We are also concerned about increasing confusion by further complicating the plan selection decisions facing beneficiaries.

Special Supplemental Benefits for the Chronically Ill (SSBCI): Medicare Rights supports the establishment of SSBCI. We hope that many plan sponsors will choose to offer these types of benefits, and thus encourage CMS to strike a balance that encourages plan innovation by providing some flexibility while also protecting beneficiaries by providing sufficient guidance and guardrails.

While we are encouraged by the potential availability of these benefits for some Medicare beneficiaries, it is important to note that this cannot be CMS’s only answer to addressing social determinants of health. With anticipated plan variation in both the type and duration of services offered, it will be difficult to address population-level needs and long-term improvements. CMS should continue to support the role that community-based organizations (CBOs) play in offering services that address social determinants of health to the chronically ill. We also encourage CMS to expand access to these services for beneficiaries enrolled in Traditional Medicare to the extent allowable by law.

Eligibility: We request that CMS provide additional clarity on the provided definition for chronically ill enrollees. Without guidance, some plans may interpret the definition too strictly, and others too broadly. We do not support plan-level flexibility on this question—a person who is determined to have a chronic condition in one plan should not find out, upon making a change during open enrollment, that they no longer meet these criteria.

Questions that require further explanation in guidance include:

- What type of chronic conditions should be considered “life threatening”? Does the chronic condition need to be life threatening currently, or have a risk of reaching that stage?

¹¹ PL 115-271 § 2005.

¹² Call Letter at 159

- What is meant by “high risk of hospitalization”? Does this refer to a risk for episodic experiences in the hospital, or to a risk for continuous hospitalization?
- What is meant by “intensive care coordination”? How does care coordination by a family member vs. a professional factor into this definition?
- Is CMS going to provide guidance on how plan sponsors and/or contracting CBOs should identify eligible beneficiaries? Will a functional, cognitive, and/or behavioral assessment be used?

A narrow reading of the definition could severely limit the impact of SSBCI. A beneficiary with a life-threatening illness may not have a reasonable expectation of improving or maintaining their health or overall function as it relates to the chronic disease. Often, the goal for frail elders is to slow decline, and meeting the goal of maintaining function could be impossible. CMS should recognize that SSBCI could significantly affect outcomes and costs for beneficiaries and plan sponsors, simply if beneficiaries avoid the need for institutional care as a result.

We appreciate the use of list of chronic conditions in the Medicare Managed Care manual as a first step and a guideline for eligible chronic conditions, but encourage CMS to provide more detail.

We also encourage CMS to revisit the determination that plans not be required to submit the process by which they identify chronically ill individuals that meet the definition in the statute.¹³ The process by which individuals are determined to be eligible or not for these services must be subject to CMS review and made publicly available in the interests of transparency and fairness, and to facilitate appeals.

Services Covered: We strongly urge CMS to encourage plans to utilize SSBCI to address social determinants of health (SDOH). When CMS expanded the scope of “primarily health related supplemental benefits,” the agency released guidance explicitly indicating that such benefits should not be used for social determinant purposes.¹⁴ We are disappointed by this guidance, which limits the ability of Medicare Advantage plans to truly address chronic health issues among enrollees. Healthy aging and wellness do not begin and end at the doctor’s office. Health status is affected by socioeconomic factors, social integration, and many other concerns outside the medical setting.

Recent research highlights the importance of SDOH in improving population health and equity. According to one analysis, social and environmental circumstances account for 20% of premature deaths.¹⁵ CMS has also completed research demonstrating the role of socioeconomic factors in clinical outcomes for beneficiaries.¹⁶ Recently, Secretary Azar even spoke about the importance of addressing SDOH, noting that a health care provider may want to help but currently can’t write a prescription for services such as healthy meals, a new home, or clean air.¹⁷ If CMS approves of SSBCI that address SDOH, this will give older adults a better chance of aging well, and will be an investment in the health of beneficiaries at the population level.

We also recommend that CMS stipulate the inclusion of Administration for Community Living-administered Older Americans Act Title III-D approved evidence-based programs in describing potential

¹³ Call Letter at 162.

¹⁴ Kathryn A Coleman, “Reinterpretation of ‘primarily health related’ for supplemental benefits,” Centers for Medicare and Medicaid Services (April 27, 2018), <https://www.nahc.org/wp-content/uploads/2018/05/HPMS-Memo-Primarily-Health-Related-4-27-18.pdf>.

¹⁵ Steven A. Schroeder, “We Can Do Better—Improving the Health of the American People,” N Engl J Med (2007), <https://www.nejm.org/doi/pdf/10.1056/NEJMsa073350>.

¹⁶ <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html>

¹⁷ <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/the-root-of-the-problem-americas-social-determinants-of-health.html>

SSBCI services.¹⁸ These programs include the suite of Chronic Disease Self-Management Education Programs originally developed at Stanford University, falls prevention programs, and depression management programs, such as Healthy IDEAS and PEARLS. Significant patient and health system outcomes have been realized from these programs, including: greater patient engagement and activation; improved medication adherence; reduced symptomatology including pain, fatigue and depression; falls and falls risk factor reduction; and health care savings through decreased ED visits and hospitalizations.¹⁹

Community-based organizations are currently delivering these proven programs to older adults and persons with disabilities in many parts of the U.S., albeit on a limited basis due to insufficient funding and the absence of Medicare incentives/coverage options and payment mechanisms. Inclusion of these programs as SSBCI services would allow Medicare Advantage enrollees with chronic illnesses to benefit more widely from these important programs that can “compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization.”

We also encourage CMS to allow plans to offer credentialed, evidence-based online chronic disease self-management programs as SSBCI. CMS should use SSBCI as an opportunity to encourage plan sponsors to cover programs such as online diabetes self-management programs (DSMP). Virtual delivery of this chronic disease program is essential for beneficiary choice as well as access (particularly for vulnerable populations or those in rural areas.) Research shows that online DSMP leads to improved health outcomes and reduced costs for beneficiaries with diabetes.²⁰

CMS should allow plans to offer services and programs like these as SSBCI:

- Supplemental Services plan development and coordination (consumer-facing; includes needs assessment and case management);
- Evidence-based health and wellness programs
- Adult day care
- Supports for family caregivers (assessments, respite care, training, etc.)
- Home safety assessments and/or falls risk assessments;
- Minor home modifications
- Nutrition services – in addition to the “home-delivered meals, food and produce” examples cited in the call letter; would also include meals provided in a congregate setting (such as an adult day or senior center), grocery provision and nutrition counseling); and
- Transportation for non-medical needs—we appreciate CMS’s inclusion of this example in the call letter.
- In-home personal care to assist with ADLs, IADLs

¹⁸ <https://acl.gov/programs/health-wellness/disease-prevention>

¹⁹ <https://www.ncoa.org/wp-content/uploads/National-Study-Brief-FINAL.pdf> and <https://www.ncoa.org/wp-content/uploads/2017-Evidence-Based-Falls-Programs-Infographic-1.pdf>

²⁰ Lorig K, Ritter PL, Turner RM, English K, Laurent DD, Greenberg J. Benefits of Diabetes Self-Management for Health Plan Members: A 6-Month Translation Study. *J Med Internet Res* 2016;18(6); Turner RM, Ma Q, Lorig K, Greenberg J, DeVries AR. Evaluation of a Diabetes Self-Management Program: Claims Analysis on Comorbid Illnesses, Health Care Utilization, and Cost. *J Med Internet Res* 2018;20(6).

CMS should also provide clarity on how the duration of a benefit will factor into the provision of SSBCI. Some benefits could have a long duration, depending on the stage of a person’s illness and type of benefit provided. It is essential to note, and to incorporate into guidance, that as discussed below, “maintenance” of an individual’s health or overall function should be included in all definitions of eligibility for SSBCI, and should be defined broadly.

Partially citing language from the Bipartisan Budget Act, CMS notes that “MA plans will have the ability to offer a “non-primarily health related” item or service to chronically ill enrollees if the SSBCI has “*a reasonable expectation of improving or maintaining the health or overall function of the enrollee as it relates to the chronic disease*” [emphasis in original].

Although not defined in the statutory language, “maintenance” should be defined broadly to include preventing and/or slowing deterioration in an individual’s condition, as is found elsewhere in Medicare rules and law. For example, the settlement in the *Jimmo v. Sebelius* litigation brought by the Center for Medicare Advocacy and Vermont Legal Aid (No. 11-cv-17 (D.VT), filed January 18, 2011) stands for the proposition that “[s]killed care may be necessary to improve a patient’s current condition, to maintain the patient’s current condition, or to prevent or slow further deterioration of the patient’s condition.”²¹

We note that later in the SSBCI section, CMS states “SSBCI under this waiver may not be provided to a chronically ill enrollee if that benefit does not have a reasonable likelihood of improving that specific enrollee’s health or overall function as related to the specific chronic illness.” CMS omits the statutory language concerning maintenance of health or overall function of an individual. In order to ensure that the broad eligibility criteria for SSBCI apply, “maintenance” language must always be used alongside “improvement” language.

As CMS has noted in the context of the *Jimmo* settlement, “Medicare has never supported the imposition of an “Improvement Standard” rule-of-thumb in determining whether skilled care is required to prevent or slow deterioration in a patient’s condition. Thus, such coverage depends not on the beneficiary’s restoration potential, but on whether skilled care is required, along with the underlying reasonableness and necessity of the services themselves.”²²

Role of CBOs: We appreciate that CMS specifically states that plan sponsors may contract with community-based organizations (CBOs) to provide SSBCI. Research has demonstrated the important role of CBOs in addressing SDOH.²³ In the recent past, there has been confusion about whether or not plan sponsors can pay for services provided by CBOs. As a result, this has caused delays in the delivery of essential services because some MA plans have referred beneficiaries to try and obtain free home- and community-based services by local CBOs. The beneficiaries and MA plans have found in these cases that there are existing “waiting lists” for such services, given the limited funding for CBOs. If MA plans more readily contract with CBOs to provide SSBCI, this will allow CBOs to meet the growing demand for the services they have long provided. MA plans can rely on the expertise of CBOs to ensure these services are provided with high quality and efficiency.

However, it is key that MA plans and CMS recognize that CBOs have a limited technical infrastructure. To ensure the greatest level of success in such contracts, many CBOs will need MA plans in the short term to help identify beneficiaries who are eligible for SSBCI. MA plans can use their infrastructure for engaging beneficiaries in services, while CBOs can focus on providing the best services possible.

²¹ https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPSP/Downloads/jimmo_fact_sheet2_022014_final.pdf; see, generally, CMS website at: <https://www.cms.gov/Center/Special-Topic/Jimmo-Center.html>

²² <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8458.pdf>

²³ <https://www.chcs.org/inside-look-partnerships-community-based-organizations-health-care-providers/>

For eligibility determinations, we recommend that CMS provide oversight and guidance to MA plans on how to allow CBOs to enroll as MA plan providers and how to facilitate their ability to determine if a beneficiary meets the eligibility requirements for SSBCI. This additional involvement is necessary because generally, MA plans only accept recommendations for plan benefits from eligible providers and many community-based organizations do not meet the requirements to become an enrolled provider. Accordingly, CBOs need a mechanism to engage with MA plans in a way that supports their ability to determine whether an individual meets the eligibility requirements for SSBCI.

Through the CHOICE Act,²⁴ NCQA and the Veterans Administration have both established a formal process to acknowledge community-based organizations as enrolled providers of long-term services and supports (LTSS). We recommend that CMS follow this precedent and acknowledge that CBOs can operate as a specialty provider type with a MA plan.

Home Modifications: CMS suggests that it will not approve of home modifications that increase property values. While we appreciate CMS's effort to avoid fraud and abuse, certain home modifications that would increase home value may also be needed to directly address a beneficiary's overall function—and would not necessarily cost more than more temporary solutions. Capital changes, such as entryway ramps, could further extend the value of durable medical equipment that CMS pays for as the individual's needs change over time. For example, as beneficiaries transition to walkers, wheelchairs, or caregiver supports, capital improvements may enable them to continue to receive care in the home, instead of moving to a facility with greater costs to deliver care.

CMS should recognize that some home modifications may not be costly investments or impact the home's value directly. For example, an occupational therapist could help a beneficiary reorganize their home to make it more functional, accessible, and safe to prevent falls. If CMS is wary of approving capital investments, at a minimum, CMS may consider establishing a dollar amount threshold for home modifications, so MA plans can offer some of these services.

Considering Other Factors: CMS should not allow SSBCI to be means tested. Though we recognize that the issue of social determinants' effects on general health is a more prominent one in lower-income populations, providing supplemental benefits like home-delivered meals reduces general health care costs in all populations. However, CMS should consider ways to incentivize plan sponsors to develop SSBCI that will specifically attract and help beneficiaries who have fewer financial resources.

Furthermore, we are concerned that plans are ill-equipped to make determinations about beneficiary income and assets, and this would increase administrative burdens on plans and beneficiaries, as well as require more significant CMS oversight.

Technical Panel: We applaud CMS's decision to create a technical advisory panel to vet the determination of chronic conditions criteria. We encourage CMS to ensure that the advisory panel's membership is diverse, including providers, the Administration on Community Living, and beneficiary advocates. This will help ensure that relevant stakeholders will have a clearer understanding of the depth of non-clinical services available to support the delivery of holistic care coordination.

Awareness and Marketing: 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. We encourage CMS to focus-group test all beneficiary materials, to require plans to adequately train call center staff to answer both general and specific questions about SSBCI, and to create and regularly update trainings for 1-800-MEDICARE, SHIPs, and SMPs to understand the scope, limitations, and beneficiary protections that apply to SSBCI.

²⁴ <https://www.va.gov/COMMUNITYCARE/programs/veterans/VCP/index.asp>

We appreciate that CMS explicitly highlights that coverage decisions about SSBCI will be subject to the regular Part C appeals process. CMS also indicates that MA plans are responsible for indicating covered services and the process for determining eligibility for SSBCI in the Evidence of Coverage. However, this is not sufficient. Detailed information about the benefits available and the coverage criteria must be publicly and easily accessible.

CMS should work with stakeholders to develop strategies to communicate about SSBCI in an effective manner, including, but not limited to, ensuring that accurate information is included in the Medicare Plan Finder tool. It is also critical that CMS establish marketing guidelines specifically around SSBCI, so plan sponsors appropriately engage beneficiaries that could benefit from these new services, without steering individuals. Even if a plan sponsor markets SSBCI towards the appropriate beneficiaries, the plan may still not be the best place for a given individual, depending on their circumstances. Thus, it is important for CMS to oversee marketing and education materials and tactics, so beneficiaries get the appropriate information to make good decisions.

Quality: It is essential that plan sponsors offer benefits which are truly helpful in addressing SDOH and chronic conditions, rather than benefits that act solely as an inducement to enrollment. As CMS and plan sponsors gain experience, CMS should monitor the offering of benefits to determine the extent to which SSBCI are actually offered and utilized, and to ensure that implementation is not directly or indirectly discriminatory. Tracking benefits and outcomes will allow CMS to evaluate the efficacy of particular SSBCI. In order to incentivize quality SSBCI, CMS should monitor the quality and outcomes of such benefits and publicly report on those findings.

Provider Directories: MA Provider Directories: Last year, CMS 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. The call letter reflects that “there has been a lack of improvement in the accuracy of provider directories over the past three years.”²⁶ Directory inaccuracies can present significant challenges for enrollees—up to and including a potential lack of access to care and significant out of pocket costs.

As such, we encourage the agency to be vigilant in its continued inquiries, oversight, and policymaking on this issue. 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. In the call letter, CMS reflects on the “common struggle expressed by the industry... that there is no... ‘source of truth.’ As a consequence, the current process of verifying the accuracy of provider information can present an undue burden on providers...”

We urge CMS to focus its attention on the undue burden that inaccurate, hard-to-access, and non-searchable provider directories place on beneficiaries. We urge CMS to consider ways to adequately incentivize plans and providers to provide accurate and up-to-date directories—perhaps by establishing special enrollment periods or indemnification for beneficiaries who relied on an inaccurate directory.

Additionally, we believe CMS’s recent findings are relevant to the implementation of the MA VBID 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 VBID model.

²⁵ 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.

²⁶ Call Letter at 164

D-SNP Administrative Alignment Opportunities: We appreciate CMS's commitment to continue to seek opportunities to create better alignment between the Medicare and Medicaid programs. Most importantly, alignment makes the programs easier for beneficiaries to navigate. It provides efficiencies for states and plans, removing obstacles to efficient delivery of care and facilitating a more coordinated response to the needs of dual beneficiaries.

Current Initiatives: Default and passive enrollment: We recognize the desire for alignment in enrollment and also appreciate that CMS has narrowed the circumstances in which passive and default enrollment occur. We continue, however, to urge CMS to require acquiescence by beneficiaries before an enrollment is finalized. Passive opt-out enrollment is simply not the appropriate start to care that seeks to be person-centered.

Flexibility in design of integrated beneficiary communications: We appreciate the work that CMS is undertaking to develop simpler and more integrated documents to communicate benefit information to plan enrollees. The financial alignment demonstration has produced some very good examples of clear communication and has also shown the confusion and backlash that can result when communications are too complex and have not been consumer tested. We strongly urge that development of integrated documents include consumer input throughout the process and that documents be subject to consumer testing. We also hope that as state-specific documents are developed in Massachusetts, Minnesota, and New Jersey, CMS shares them and the learning from their development with other states and provides guidance for best practices.

Sharing plan performance information and audit results: We very much appreciate this initiative. Performance and audit information will assist states in deciding whether to contract with proposed D-SNPs. Further, this information will help states understand the strengths and weaknesses of the plans with which they do contract, which should assist both in contract negotiation and plan oversight.

Integration of state expectations into Models of Care: Our experience is that Models of Care (MOCs), though potentially important vehicles for driving innovation, have not yet lived up to their potential. A process for incorporating state expectations and aligning models of care with commitments in state contracts could certainly help to make the MOCs more robust instruments. We are not aware of how the timelines for state contracting processes and timelines for developing and getting CMS approval for Models of Care mesh but suggest that they be synchronized.

Currently D-SNP MOCs, though publicly available, are not easy to find. To our knowledge, D-SNP reports of their implementation and any CMS evaluations are not available at all. The value of MOCs could further be strengthened if more information were easily available and if the MOCs and the D-SNPs' progress in implementing them were routinely incorporated into the stakeholder engagement process.

We also note the challenges of creating meaningful MOCs for D-SNPs that enroll both full and partial dual eligibles. If CMS and/or states decide to permit D-SNPs that enroll partial duals, we ask that CMS pay particular attention to whether the MOC addresses the needs of both populations.

Proposed additional areas: Durable Medical Equipment (DME): DME alignment faces multiple challenges. Where D-SNPs operate in states with fee-for-service Medicaid or where individuals are enrolled in a non-matching Medicaid managed care plan, beneficiaries may face the need to use multiple DME suppliers unless the D-SNP network suppliers also are enrolled in the state Medicaid program. Even when a D-SNP has a matching Medicaid managed care product, there is no current requirement that DMS suppliers align. We urge CMS to consider requiring supplier alignment.

Streamlining the information requested from providers to support DME approval is another area of alignment. Whether or not the D-SNP has a matching Medicaid plan, it would be helpful if the supporting information collected from the prescriber included all that is needed for either Medicare or Medicaid review. Ideally, there would be a single form that would be acceptable to both the D-SNP for Medicare

review and to the state Medicaid program and/or its managed care plans. This would lessen the burden on prescribers and avoid delays when Medicaid review is needed.

Alignment of supplemental benefits with Medicaid coverage: We have continuing concerns about ensuring that supplemental benefits offered by D-SNPs complement but do not overlap with Medicaid-covered services. We have seen many problems where, for example, beneficiaries are enrolled in Medicare Advantage plans that offer partial dental or vision coverage that overlaps with more extensive Medicaid coverage although provider networks do not overlap. To promote alignment, we ask CMS to review the supplemental benefit packages proposed by D-SNPs and only approve services that complement, rather than duplicate Medicaid coverage.

Further, if a D-SNP offers supplemental benefits that do, in fact, complement Medicaid coverage, beneficiaries ought to be able to use the same provider and not have to jump between a D-SNP provider and a Medicaid provider for different treatment needs. This issue arises with dental coverage but can appear in other areas as well, such as transportation benefits. An MA plan might offer transportation to senior centers or to a pharmacy to supplement non-emergency transportation Medicaid benefits that offer rides to medical providers. If beneficiaries do not have one number to call, they may well be charged for using the wrong service or be denied transportation they believed was covered.

Several steps might help with this provider alignment. The ideal alignment would be for all D-SNP providers to be enrolled in the state Medicaid program. We recognize, however, that such a requirement may interfere with the D-SNP's ability to recruit a robust provider network. We propose that CMS consider some additional potential avenues to address the issue. For example, states could provide D-SNPs with the identities of all their contracted service providers that might overlap so D-SNPs could consider recruiting them to join their networks.

We have also thought about the procedure used by some states to offer abbreviated short-form applications for providers who seek Medicaid enrollment solely for purposes of receiving crossover claim payment for QMB beneficiaries. States could consider offering abbreviated—or automatic—enrollment for D-SNP providers solely for the purpose of providing Medicaid-covered services to members of the D-SNP. For example, in a D-SNP offering supplemental dental services, the state could enroll the D-SNP dentist in Medicaid with little or no paperwork with the limitation that the dentist's Medicaid enrollment only covers services provided to D-SNP members. This would allow a D-SNP member to use one provider for an entire oral health treatment plan but would also accommodate providers unwilling to serve Medicaid patients more generally. We expect that if this approach were pursued, it would require guidance from CMS endorsing the procedure.

Language access: In the dual eligible demonstrations, the three-way contracts required that translation requirements for beneficiary communications meet either state or federal requirements, whichever were most beneficiary to the enrollee. This common-sense requirement ensures that beneficiaries consistently get the same level of language access for both their Medicare and Medicaid benefits. We ask that CMS make this a requirement for all D-SNPs.

Coordinated State-Federal oversight: In the dual-eligible demonstrations, we have seen real value in the use of federal-state Contract Management Teams (CMTs) that meet regularly to review ongoing progress and also are available when issues arise that need to be addressed. We believe it is important to put similar mechanisms in place for state D-SNP programs to ensure consistent oversight and coordination between state and federal regulators and to work out any issues arising from inconsistencies or misunderstanding in regulatory directives.

State commitment to alignment: In states where Medicaid services are provided in a fee-for-service program or where some services are carved out from Medicaid managed care, it is critical that states make a commitment to support alignment of services and back that commitment with concrete actions.

To improve alignment, states could require, in their contracts with entities providing carved out services and their contracts with all Medicaid managed care organizations, that those entities enter into information sharing agreements with D-SNPs in the state and that Medicaid providers participate in care coordination activities. States may need to include the added costs of coordination in their contracts with those entities.

Aligned business practices: In the dual-eligible demonstrations, we saw significant problems in alignment of business practices between providers of Medicaid-covered services and demonstration plans. Perhaps the most striking example was in Ohio. There, the way that home care providers recorded their time did not mesh with how managed care plans handled payment, with the result that many providers, themselves low-income individuals, were not paid. Many home care providers reluctantly left their jobs and many beneficiaries lost providers, at least until the plans and state ultimately developed solutions.²⁷ There have also been multiple less dramatic instances of adult day health programs and other key providers facing cash flow shortfalls because of technical issues with payments from demonstration plans. These nuts and bolts issues are critically important, especially because many providers of home and community-based services are nonprofits with limited resources to weather temporary financial storms. We appreciate that CMS has supported technical assistance in these areas and urge continued attention to these issues, including specific guidance to plans regarding their obligations to identify and work out technical issues with contracted providers before, rather than after, commencing services to beneficiaries.

Ombuds Programs: The success of ombuds programs in the financial alignment demonstrations has shown the need for and value of beneficiary assistance that can address both Medicare and Medicaid issues. In the dual-eligible demonstrations, ombuds programs have proven invaluable in identifying systemic problems as well as assisting in individual cases. In many instances, the ombuds have been able to avoid appeals by identifying administrative or technical problems that led to a denial. We strongly urge CMS to establish dual eligible ombuds in states with D-SNPs and to support them both financially and with technical assistance.

Working level alignments: There is much room for alignment at the granular level. For example, though we recognize that a universal health risk assessment tool is an ideal not yet reached, we do believe that there is much that could be done in the short and medium term to ensure that D-SNP assessments use the same terminology as state Medicaid programs, and that D-SNP coordinators are fully aware of state Medicaid requirements. Similarly, data collection should use categories that coordinate with Medicaid data collection, as well as categories that can be compared across data systems and across plans and states.

D-SNP “Look-alikes”: We echo the serious concerns our partner organizations, including Justice in Aging, have raised based on their experience in California. Here, we echo some of their comments and concerns about D-SNP look-alikes. We believe that CMS should do all that it can to stop the marketing of these products, which do not genuinely serve the needs of duals and interfere with the development of truly integrated products that are subject to specific rules and oversight.

To start, however, we note that no health insurer is required to enter the Medicare market. They choose to do so because the market can be profitable. For the privilege of participating in Medicare Advantage, it is reasonable for CMS to require a basic commitment to support and not interfere with the broader goals of the agency, including its goal to serve the needs of dual eligibles by coordinating their Medicare and Medicaid benefits. CMS and the states are working on many models to achieve these goals including Medicare-Medicaid plans, managed fee for service coordination, D-SNPs, and PACE. Congress has supported those efforts throughout, by establishing the Medicare-Medicaid Coordination Office, permanently authorizing D-SNPs, and establishing and funding demonstration authority for CMMI. It is only reasonable and well within the scope of CMS’s authority for the agency to require that any plan

²⁷“Local News Calls Attention to Rollout Problems with MyCare Ohio”
<http://hosted.verticalresponse.com/1027935/98dc1bf217/520801381/b6f64edfca/>

sponsor wishing to specifically target the dual-eligible market do so only by offering products that CMS has determined appropriate for dual eligibles and that are regulated by CMS as dual-eligible products.

Impacts of look-alikes: *Beneficiary engagement:* The dual demonstrations have included multiple opportunities for stakeholder involvement in plan design and execution, both in planning and throughout the plan implementation. Structured engagement of beneficiaries and their advocates has both empowered beneficiaries and led to significant innovation in the demonstrations. See, for example, the work of the Implementation Council and the involvement of Disability Advocates Advancing our Health Care (DAAHR) in the One Care dual-eligible demonstration in Massachusetts.²⁸ Though the situation with D-SNPs currently is mixed, we expect that future state contracts will also require these plans to incorporate beneficiary voices, a requirement that is particularly important for the diverse individuals served by D-SNPs. No such structure is required or, to our knowledge, exists with look-alikes.

MA plan sponsor commitments: CMS, states, and beneficiary advocates entering into the dual eligible demonstrations had an expectation, that participating plan sponsors were fully committed to the demonstrations. Yet it appears that some of those sponsors acted to create competing products and put as much or more effort into recruiting members for those competing plans. More generally, the divided loyalties of some plan sponsors inevitably lead to questions about the extent to which plan sponsors fully support integration. Our concerns are similar with respect to plan sponsors that do not offer D-SNPs and do not participate in dual eligible demonstrations but instead aggressively seek out dual-eligible beneficiaries while skirting the regulatory framework designed to support the goals of integration. They too draw beneficiaries away from more integrated options, and confuse the market without offering added value.

Providers/improper billing: We are not privy to how look-alike plans negotiate with their providers and are concerned about this process. If a provider looks at the plan design on paper and decides to join the plan network, that provider would reasonably expect that, besides the contractual amount received from the plan, the provider would collect significant co-insurance amounts from most plan members. In fact, looking at MedPAC numbers,²⁹ over 90% of the time the provider would be prohibited from collecting any amount because of the enrollee's dual status. Further, given the "lesser of" policy with respect to Medicaid payments for QMBs and the current difficulties for Medicare Advantage providers in even filing for such payments, the provider would almost always receive nothing or next to nothing from any source other than the contracted amount from the plan. We question whether look-alike plans have shared this financial reality with providers when negotiating rates and, if not, whether the failure to do so was a material misrepresentation to providers. We also question whether plan design and cost and benefit projections presented to CMS when seeking approval for their look-alikes genuinely reflected the easy-to-anticipate and disproportionate loss of co-insurance income by providers.

From a beneficiary point of view, a plan with high co-insurance amounts that are actually phantom substantially increases the risk of improper billing. Similarly, though providers are contractually prohibited from discriminating against plan members protected from improper billing, we have serious concerns that look-alike network providers will find ways to avoid serving look-alike plan members who cannot be charged cost sharing so they can focus on more profitable patients, either inside or outside of the look-alike plan.

²⁸ See Implementation Council site at www.mass.gov/service-details/one-care-implementation-council and DAAHR site at <https://bostoncil.org/advocacy/daahr/>; see also discussion at Kaiser Family Foundation, "Early Insights from One Care: Massachusetts' Demonstration to Integrate Care and Align Financing for Dual Eligible Beneficiaries (May, 2018), www.kff.org/medicaid/issue-brief/early-insights-from-one-care-massachusetts-demonstration-to-integrate-care-and-align-financing-for-dual-eligible-beneficiaries/.

²⁹ June 2018 MedPAC Report to Congress, pp. 276-281, available at http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.

Impact on counselors: It is our experience that look-alikes have confused SHIP counselors and other advocates who assist beneficiaries in navigating their Medicare choices. In many cases counselors had no idea that look-alikes were operating in their area. The lack of transparency about these plans made it difficult for counselors to provide informed advice.

Impact on integration: We are concerned that the promotion of look-alikes has had a serious impact on the development and sustainability of integrated care products for dual eligibles. In demonstration states, stakeholders; states; and CMS spent countless hours developing duals-specific consumer protections, setting care coordination standards, smoothing the appeals process for services that might cross Medicare and Medicaid, establishing reporting requirements and oversight mechanisms, and much more. Yet look-alikes swept into the market with no transparency and no state contracts. None of the protections and requirements in the demonstrations applied to look-alikes and they faced no real accountability for their service to dual eligibles. In California, though the state tried to clear the way for a vigorous demonstration by limiting D-SNPs in demonstration counties, the look-alikes largely negated that effort, enrolling almost as many beneficiaries as were enrolled in the demonstration. They effectively stunted the growth of the demonstration and, by convincing dual beneficiaries that their plans were appropriate for them, deprived duals of the opportunity to join a plan that actually met requirements for integrated care.

Impact on evaluation of demonstrations: Particularly because they were under-the-radar through much of the demonstration, the look-alikes skewed analysis of enrollment dynamics in demonstration counties. In California, for example, much of the narrative in the early years of the demonstration was around blaming lower than expected enrollment on beneficiaries who refused managed care and their providers who scared their patients away from the demonstration. In fact, it was the plans that were strategically and systematically enrolled people into alternative products and many patients of those providers ended up in look-alikes.

Addressing the problem: We urge CMS to work to eliminate look-alikes or curtail them as much as possible. We stress that the rise of look-alikes and their negative effects on beneficiaries and on integration efforts is the result of plan actions, not beneficiaries,' and that efforts to fix the problem should focus on plans. We find it distressing that some solutions proposed by some D-SNPs and demonstration plans, and echoed by MedPAC,³⁰ put the onus on the beneficiary—initiate more passive enrollment, lock the beneficiary in, limit opportunities to change. Beneficiaries did not create this issue, plan sponsors did. They took advantage of Medicare Advantage rules so they could offer plans targeting dual eligibles without conforming to the requirements that CMS and states have put in place to ensure that plans serve this population well.

As the call letter notes, CMS can use its authority under 42 C.F.R. 422.2268 to prohibit misleading communications by plans. We also urge that CMS, by regulation, use the broad authority under 42 U.S.C. 1395w-26(b), to rein in look-alikes.

We support CMS's commitment to closely monitor look-alike marketing both for misrepresentations and for possible violations of non-discrimination requirements. We also urge CMS to look closely at bid submissions from look-alike plans to understand the underlying financial assumptions in those bids and their validity in light of the fully predictable lopsided plan enrollment patterns. We offer the following additional suggestions of measures that, separately or in combination, may be effective:

D-SNP classification: CMS should treat any plan with membership of at least 80% dual eligibles as D-SNP subject to the regulatory requirements for D-SNPs, including the requirement for a contract with the state. Since an 80% membership means that a plan's membership is overwhelmingly dual eligibles, we believe this approach is consistent with Congressional intent in the D-SNP definition in 42 U.S.C. 1395w-28W(b)(6).

³⁰ June 2018 MedPAC Report to Congress, pp. 276-281, available at http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.

Contractual commitments: Require that any plan sponsor seeking a contract to offer an integrated product agree, as a condition of the contract, that the sponsor will not offer a non-integrated product in the same service area that enrolls more than 25% dual eligibles and/or has a plan design that appears to be particularly attractive to dual eligibles. CMS could set parameters on the design elements subject to this requirement.

Marketing materials: Require that plan agents and brokers, when engaging in one-on-one or small group marketing for an MA plan that is not a D-SNP or demonstration plan, must determine whether the beneficiary is a dual eligible and, if so, must clearly explain both orally and in writing that the plan is not an integrated product and does not have a contract with the state to coordinate Medicaid benefits, as well as what that means for the beneficiary. If there are integrated products being offered in the plan service area, the written document must list them and their contact information. The written document should be a standard document prepared by the plan and reviewed by CMS and other stakeholders, including beneficiaries and their advocates.

Outbound Verification Call: Upon receipt of the application of a dual, the plan must initiate an outbound verification call to confirm that the dual-eligible beneficiary understands the limits of the plan. The plan representatives should be trained on how any supplemental benefits offered by the plan overlap or interact with the Medicaid benefits in that state and affirmatively offer assistance to the beneficiary in understanding this basic relationship. Any dual eligible who enrolls in a non-integrated plan should at a minimum understand how the plan does and does not coordinate Medicaid benefits.

Education of SHIP counselors: CMS can provide regularly updated materials and trainings for SHIP counselors on the availability of integrated products in their area and the identity of non-integrated products with high dual-eligible enrollment.

Provider notice: Require that when a non-integrated plan has, expects to have, or based on its design is reasonably likely to have an enrollment of more than 25% dual eligibles, the plan must provide special notice to prospective and current in-network providers stating that the providers will be prohibited from collecting co-insurance from a significant percent of their patients; explaining how providers can seek payment from state Medicaid programs; explaining the limits of the “lesser of” policy; and fully explaining improper billing protections as well as the duty of providers not to discriminate against plan members on the basis of payment source.

Appeals: We fully support CMS efforts to create a more unified appeals system for duals.

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 HETS system.

The reports 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. For example, we continue to hear about plan providers who do not understand the protections or are unwilling to honor them, and about plan representatives who do not understand or fulfill their obligations to protect members. Thus, CMS’s continued emphasis in this call letter on plan obligations to educate providers and to continue to develop tools to better effectuate QMB protections 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.

Medicare Advantage Organizations Crossing Claims over to Medicaid Agencies: We agree with CMS that the current system—or more precisely, lack of a system—for handling crossover claims from providers in MA plans to Medicaid creates serious challenges.

Although we know of no published data on how states handle claims by MA plan providers, it appears that most states have no policy at all or, if they do, it is not laid out transparently. We understand that a handful of states give plans capitated amounts to account for the states' QMB payment obligations but do not know if or how any of those amounts are passed to the providers who actually serve the QMBs and are prohibited from collecting co-insurance.

According to the QMB statutory provisions, the obligation of states to pay deductibles and co-insurance flows to the provider, either directly or indirectly. The loss of deductibles and co-insurance falls on the provider, not the MA plan, and thus it is the provider whose interests are protected by the statute. Thus, it is not enough for states to pay something to MA plans without there being some assurance, whether enforced by CMS or otherwise, that providers be the parties that are ultimately compensated for their services to QMBs.

Implementing an automated crossover process from MA plans to the appropriate Medicaid secondary payer is more practical and less burdensome than requiring each provider to navigate the system independently. Our understanding, however, is that currently plans do not have information from the states or from CMS on the identity of the Medicaid plan to which the beneficiary belongs. Thus, MA plans would have to rely on the beneficiary for that information, which may not always be accurate. For more reliable records, states would need to institute a process to transmit MCO membership data to MA plans and to update information when an individual changes MCOs.

A better solution would be for all crossover claims to go to one central processing center. As we think more generally about the complexities of crossover claims, including the issues raised by CMS in its proposed revision to 42 C.F.R. 438.3(t),³¹ we are increasingly convinced that the most efficient way for states to handle crossover claims is for states to retain within the Medicaid agency the responsibility for processing all crossover claims, whether or not the state relies on MCOs for delivery of Medicaid services. After all, payment of crossover claims is purely an accounting function that does not require any determination of medical necessity or any specialized expertise. Delegation to MCOs creates complexities without any tangible benefit.

In any case, to fulfill their statutory obligation to process payment claims for QMB services, states have an obligation to create a system that is accessible and functions with reasonable efficiency.

It is important to ensure that the benefits of a state QMB payment system accrue to the providers. This is especially true because providers serving QMBs already face limited remuneration because of the "lesser of" payment policy, which can create access problems or disproportionately burden providers. Particularly in the managed care context where providers are prohibited from denying service to QMBs, it is important that those providers with a significant number of QMB patients are treated fairly. If they are not, beneficiaries are more likely to experience improper billing or attempts by providers to skirt their obligation to serve QMB plan members.

Thus, though crossover claims can be processed efficiently if funneled through the MA plan, there also should be safeguards to ensure that providers get the benefit of the state payments and that payments are not retained by the MA plans.

Request for Information—Barriers for MA Plans or Providers in using Risk Based Arrangements for Pharmacy Benefits: In a continued effort to reduce drug costs, CMS is requesting comments on potentially using risk-based arrangements for pharmacy benefits in contracts between MA plans and providers. The agency states these types of arrangements may help decrease Part B drug costs in MA and Part D drug costs in MA prescription drug (MA-PD) plans,³² but wants to hear about the barriers,

³¹ See 83 Fed.Reg. 57264, 57265 (Nov. 12, 2014) available at www.govinfo.gov/content/pkg/FR-2018-11-14/pdf/2018-24626.pdf.

³² Call Letter at 171.

feasibility, and benefits/drawbacks with these types of arrangements. Given the very limited information provided on this issue in the call letter, we are unable to provide comprehensive comment. We look forward to additional information about the rationale behind the request and specific questions that CMS would like stakeholders to answer.

In general terms, we are not opposed to risk sharing arraignments with providers that adequately capture both immediate and long-term risks and benefits—and those that have sufficient beneficiary protections so that prescriber independence and beneficiary rights to exceptions and appeals are not impinged. Particularly in light of the requirement of prescriber support for exception requests in Part D, we would be concerned with any risk-sharing scheme that rewarded providers for staying on-formulary or penalized support for an exception to plan rules where medically required.

Improving Access to Opioid Reversal Agents: We strongly support CMS’s efforts to improve access to the potentially lifesaving drug Naloxone, and to encourage plans to place Naloxone on a generic or zero-dollar cost-sharing tier.

Access to Medication-Assisted Treatment (MAT): Medicare Rights supports CMS’s efforts to ensure appropriate access to MAT and to scrutinize formulary and benefit submissions to ensure that “benefit designs that would substantially discourage enrollment by beneficiaries who need these therapies” not be approved.³³ We appreciate CMS’s reminder that “drug addiction may be considered a disability under Federal civil rights laws and a covered entity is required to provide nondiscriminatory access to its healthcare programs, including evidence based opioid use disorder treatment and recovery services.”³⁴

Part D Benefit Parameters for Non-Defined Standard Plans

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 VBID 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, including by releasing information on its review process, on notable or common circumstances where potentially discriminatory practices are uncovered, and other circumstances. This is particularly important given trends concerning the increasing use of coinsurance for high-cost medications.

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 possible future adjustments, but disagree with maintaining the current threshold. We urge the agency to immediately raise this level to address the disproportionate number of drugs that are out of reach because of their placement this tier. 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.

³³ Call Letter at 175

³⁴ Id.

We therefore strongly urge CMS to raise this threshold, and to prioritize the completion and public release of the agency’s anticipated analysis 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” as outlined in the 2018 call letter.³⁵ With respect to tiering exceptions, we hope the following questions will be included as part of CMS’s review:

- 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?

Improving Access to Generic and Biosimilar Medicines: “In order to encourage utilization of more affordable generics and lower out-of-pocket costs for seniors and avoid beneficiary confusion” CMS is considering an alternative to the existing tier composition policy which would discourage or prohibit plan sponsors from placing generics on brand formulary tiers and brand drugs on generic formulary tier.³⁶ This alternative would eliminate the non-preferred drug tier.

We support this proposal, which would require Medicare Part D prescription drug plans (PDP) to automatically include generic and biosimilar medicines on generic formulary tiers right after they are launched, and require generic drugs to be on generic tiers and brand name drugs to be on brand tiers. The current policy has arguably resulted in reduced sales of lower cost generics and biosimilars and if left unchanged, could cause less innovation and launches of generics and biosimilars in the future. This proposal would make generic prescription drugs and biosimilars more accessible for beneficiaries by reducing their, and the Part D program’s, costs.

Generics and biosimilars play an important role in lowering prescription drug prices and ensuring that consumers have access to affordable medicines. Generics saved consumers \$253 billion in 2016³⁷ and according to the Rand Corporation, biosimilars could reduce biologic spending by \$54 billion by 2026 if they could compete on a level playing field.³⁸ Generics account for the vast majority of prescriptions, and the average primary copay for a generic drug is \$6.06, while the average primary copay for a brand drug is \$40.30.³⁹

Over the course of time, however, Medicare Part D PDPs started to move generic drugs into higher tiers, which resulted in higher copays and out of pocket costs for consumers and higher costs for the federal government.⁴⁰ According to a recent Avalere study, from 2011 to 2015, generic drugs have increasingly

³⁵ Advance 2018 Rate Notice and Call Letter, p. 144.

³⁶ Call Letter at 180.

³⁷ Association for Accessible Medicines. 2017 annual report. www.accessiblemeds.org/resources/reports/2017-aam-annual-report.

³⁸ Mulcahy, A.W., Hlavka, J.P., and Case, S.R. “Biosimilar Cost Savings in the United States: Initial Experience and Future Potential.” Santa Monica, CA: RAND Corporation, 2017. <https://www.rand.org/pubs/perspectives/PE264.html>.

³⁹ Association for Accessible Medicines. 2018 *Generic Drug Access and Savings in the United States*. 2018. Available at https://accessiblemeds.org/sites/default/files/2018_aam_generic_drug_access_and_savings_report.pdf.

⁴⁰ Avalere Health. *Generic Drugs in Medicare Part D: Trends in Tier Structure and Placement*. May 22nd, 2018. Available at <https://avalere.com/press-releases/seniors-pay-more-for-generics-in-medicare-prescription-drug-plans-despite-stable-prices>.

been moved to higher tiers, increasing costs.⁴¹ Indeed, total out of pocket patient costs for the same group of generic drugs increased by \$6.2 billion between 2011 and 2015, an increase of 93%.⁴² The increase in out-of-pocket cost associated with the movement from tier 1 to higher tiers happened for generics even though generic list prices were stable and in some cases actually decreasing.⁴³ Indeed, the Government Accountability Office reviewed the price trends of generics from 2010 to 2015 and found that generic prices declined by 59% for all drugs and declined by 14% for a subgroup of generics.⁴⁴

In summary, we support the proposed alternative tiering policy, which would require Medicare Part D PDPs to separate generics and branded drugs on their drug formularies by automatically including generic medicines on generic tiers and keeping brand drugs in brand tiers. This action should save seniors and the federal government significantly. CMS should reduce the complexity of formularies and tiers, and adopt policies that simplify shopping for and comparing plans.

Thank you again for the opportunity to comment on these proposals.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Baker". The signature is fluid and cursive, with the first name "Joe" being more prominent than the last name "Baker".

Joe Baker
President
Medicare Rights Center

⁴¹ Id.

⁴² Id.

⁴³ Id.

⁴⁴ Government Accountability Office. *Generic Drugs Under Medicare*. August 2016. Available at <https://www.gao.gov/products/GAO-16-706>.