Center for Medicare Advocacy
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Via Electronic Submission to www.regulations.gov

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-4182-P - Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2019

Dear Administrator Verma:

The Center for Medicare Advocacy (Center) is pleased to provide the Centers for Medicare & Medicaid Services (CMS) with comments on the proposed rule entitled Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefits Programs for Contract Year 2019 (CMS-4182-P). The Center, founded in 1986, is a national, non-partisan law organization that works to ensure fair access to Medicare and quality healthcare. At the Center, we provide education and advocacy on behalf of older people and people with disabilities to help secure fair access to necessary health care. We draw upon our direct experience with thousands of individuals to help educate policy makers about how their decisions affect the lives of real people. Additionally, we provide legal representation to ensure that people receive the health care benefits for which they are eligible, and for the quality health care they need. We also submit these comments on behalf of California Health Advocates (www.cahealthadvocates.org).

Note that the following comments are organized in two sections: I. Changes to Medicare Advantage Benefits Requirements, which address sections II. A. 2, 3, 4, 5 and 6 of the preamble to the proposed rule; and II. Other Proposed Changes to Medicare Advantage and Part D, which address some of the remaining elements of the proposed rule.

I. Proposed Changes to Medicare Advantage Benefits

Overarching Comments

The preamble to the proposed rule states that "this regulation meets the Administration's priorities to reduce burden and provide the framework to develop MA and Part D products that better meet the individual beneficiary's healthcare needs." (p. 56339) While much of these

proposed changes appear to be aimed directly at assisting plan sponsors by reducing their obligations and oversight, we are unconvinced that beneficiaries will so benefit.

We draw upon our experience providing direct representation to Medicare beneficiaries. We have long advocated for more standardization of MA plan benefit packages and cost-sharing in order to make plans easier to shop and compare for those who wish to enroll in MA. These proposed changes, some of which are untested, will make things more complex, not less, for beneficiaries. Beneficiary "choice" and plan "flexibility" should not be stand-ins for adequate consumer protections. The processes for offering and selecting private Medicare plans should not be designed for the savviest consumer; rather, there must be standard, baseline means of plan comparison.

There exists a large body of research and analysis that explores the challenges consumers currently face in making choices about their health insurance coverage, including when there are multitude of plan options, with little to no standardization.[1] Much of the findings in this work weigh against CMS' proposals outlined in the NPRM, primarily those that would loosen both uniformity and meaningful difference standards.

There is much work to be done to address current methods of beneficiary decision-making, including enhancing consumer-directed tools. In response to CMS' Request for Information attached to the 2018 Call Letter, the Center, along with other consumer advocates, outlined some

[1] Here is a sample of such research and analysis: "Realizing Health Reform's Potential : What States Are Doing to Simplify Health Plan Choice in the Insurance Marketplaces"*;* Christine H. Monahan, Sarah J. Dash, Kevin W. Lucia, and Sabrina Corlette; *The Commonwealth Fund*, December 2013 (available at: http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2013/Dec/1720_Monahan_what_states_are_doing_simplify_rb.pdf); "The Evidence is Clear: Too Many Health Insurance Choices Can Impair, Not Help Consumer Decision Making", Lynn Quincy and Julie Silas; *Consumers Union*, November 2012 (available at: http://consumersunion.org/wp-content/uploads/2012/11/Too_Much_Choice_Nov_2012.pdf); "What's Behind the Door: Consumers' Difficulties Selecting Health Plans" Lynn Quincy; *Consumers Union*, January 2012 (available at: http://consumersunion.org/wp-content/uploads/2013/03/Consumer_Difficulties_Selecting_Health_Plans_Jan2012.pdf); "Cognitive Functioning and Choice between Traditional Medicare and Medicare Advantage"; J. Michael McWilliams, Christopher C. Afendulis, Thomas G. McGuire, and Bruce E. Landon; Health Affairs, September 2011 (available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3513347/);"Medicare Part D: Simplifying the Program and Improving the Value of Information for Beneficiaries", Jack Hoadley; *The Commonwealth Fund*, May 2008 (available at: http://www.commonwealthfund.org/Publications/Issue-Briefs/2008/May/Medicare-Part-D--Simplifying-the-Program-and-Improving-the-Value-of-Information-for-Beneficiaries.aspx); "Medicare Advantage: Options for Standardizing Benefits and Info to Improve Consumer Choice", Ellen O'Brien and Jack Hoadley; *The Commonwealth Fund*, April 2008 (available at: (http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2008/Apr/Medicare%20Advantage%20%20Options%20for%20Standardizing%20Benefits%20and%20Information%20to%20Improve%20Consumer%20Choice/OBrien_Medicare_Advantage_options_1117_ib%20pdf.pdf); and "Informed Choice: The Case for Standardizing and Simplifying Medicare Private Health Plans," Precht, P., Lipschutz, D. and Burns, B. (California Health Advocates and Medicare Rights Center: September 2007), available at: http://cahealthadvocates.org/_pdf/advocacy/2007/InformedChoice.pdf.

ongoing suggestions to strengthen educational tools and beneficiary supports.[2] These suggestions include:

- Strengthen State Health Insurance Assistance Programs (SHIPs) – SHIP counselors are essential to helping people with Medicare make informed, individualized choices about how to receive coverage and care, and offer increasingly critical services that cannot be supplied by 1-800 MEDICARE or through web-based and written materials. Rather than cut funding for the SHIP network, as has been proposed by this administration, we urge greater investment in this vital, cost-effective program. We note that throughout the proposed rule, SHIPs are hardly mentioned, if at all, despite being an integral resource for Medicare beneficiaries.
- Improve Notices: we encourage CMS to continue to develop model notices in consultation with numerous stakeholders, including consumer advocates. Where CMS does not require MA and Part D plans to use model notices, plans should be encouraged to test notices and to report on such testing to CMS. Additionally, CMS should improve communications with individuals with limited proficiency in English.
- Promote Active and Informed Plan Choice: CMS should advance policies that encourage people with Medicare to make active and informed choices about the coverage option(s) that are right for them, selecting among Traditional Medicare, Medicare Advantage plans (including integrated Medicare-Medicaid options), supplemental Medigap policies, and stand-alone Part D prescription drug plans. Such improvements should include:
    - An individualized MA and Part D Annual Notice of Change (ANOC) to better serve beneficiary needs, specifically one that details which specific providers or pharmacists 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, reflecting an individual's actual providers, pharmacists, services, and prescription drugs);
    - Revitalize the Medicare Plan Finder - incorporate a searchable MA provider directory in Plan Finder that includes both individual practitioners and hospitals. Clearer information on cost-sharing and coverage for MA supplemental benefits, like dental and vision care, is also needed. Further, CMS should add information on Medigap options to Plan Finder to allow beneficiaries to fully assess the coverage choices available to them. Engage in a transparent, multi-stakeholder process to solicit input on needed Plan Finder improvements and how best to redesign this important consumer tool.
    - Standardize MA Plan Benefit Packages – most relevant to this proposed rule, we continue to point out that many people struggle to select among several MA plans and multiple, complex plan variables. To encourage efficient plan selection,

[2]Center Comments on Medicare Advantage and Part D "Transformation Ideas" April 25, 2017, available at: http://www.medicareadvocacy.org/center-comments-on-medicare-advantage-and-part-d-transformation-ideas/.

distinctions among plans must be made more meaningful. We strongly support CMS' ongoing efforts to eliminate plans too alike to other plans offered by the same insurer, and we encourage the agency to continue in this manner. At the same time, CMS should consider standardizing MA benefit packages, like the rubric required for supplemental Medigap plans (i.e., Plan A, Plan B, Plan C), to encourage "apples-to-apples" comparisons among plan options. Confusion surrounding Medigap policies – both concerning benefits offered and value for premiums paid – significantly diminished when Medigap plans were standardized. Medicare beneficiaries shopping for and comparing MA plans would similarly benefit from being able to compare standardized MA benefit packages between and among plan sponsors.

In the Center's comments to the RFI, we also outlined suggestions to strengthen and preserve essential consumer protections in the MA program[3], including:

- Access to providers – We applaud CMS' recent efforts to address MA network adequacy by planning to review such networks on three-year cycles rather than only when a company applies for or renews their status in the program, along with conducting intermediate full network reviews under certain circumstances. We also appreciate steps CMS has taken to address inaccurate MA provider directories. Given that one of the most important health care considerations for an individual is the ability to choose one's doctor(s) and other health care providers, and that, by design, MA plans generally contract with a limited network of providers to care for their enrollees, much more needs to be done in order to ensure that plan enrollees have meaningful access to, and information about, network providers. We urge CMS to implement the remaining recommendations outlined in the General Accounting Office (GAO) 2015 report on MA network adequacy, including expanding the definition of network adequacy, verifying provider information submitted by plans and setting minimum information requirements for plan enrollee notification letters.[4] In addition, CMS must do more to address the issue of provider network terminations and their impact on beneficiaries. Absent prohibiting mid-year provider network terminations without cause, which we advocate for, CMS should improve advance notice given to beneficiaries and expand the current limited special enrollment period (SEP) right applicable to certain affected individuals.
- Increase plan sponsor oversight – as noted in our comments to the RFI, we strongly believe that robust consumer-oriented regulations, ongoing monitoring and evaluation,

[3] For more information, including additional detail about these recommendations, see the Center's Comments on Medicare Advantage and Part D "Transformation Ideas" April 25, 2017, available at: http://www.medicareadvocacy.org/center-comments-on-medicare-advantage-and-part-d-transformation-ideas/.
[4]General Accounting Office (GAO) report: "Medicare Advantage: Actions Needed to Enhance CMS Oversight of Provider Network Adequacy" (August 2015, publicly released September 28, 2015), available at: http://www.gao.gov/products/GAO-15-710.

and a reliance on transparent processes to guide any proposed changes to administrative policies are integral to the ongoing participation of private plans in the administration of the Medicare Advantage and Part D programs. Such effort should include enhanced audit capacity and increased transparency on enforcement actions, and further alignment between plan Star Ratings and enforcement actions.

As noted above, CMS has made some progress with respect to addressing issues with MA network adequacy. Also, as discussed below, we appreciate that CMS proposes to significantly scale back the scope of MA seamless conversion enrollment. However, the proposed changes in this rule allowing greater plan flexibility while at the same time limiting the scope of CMS oversight and plan compliance in certain areas (e.g., review of plan materials, compliance programs re: training requirements, changing rules concerning enrollee receipt of paper materials, loosening MLR requirements) all combine to both abdicate oversight responsibility and increase beneficiary confusion. At a time when many MA plans are still collecting inappropriate, inflated payment due to "upcoding", and there is a growing body of evidence that MA plans might not serve sicker beneficiaries as well as healthier people[5], CMS should not cater to plan requests to reduce "burden" but should instead redouble efforts to ensure that MA plan enrollees, and the broader Medicare population, are being well served by the Medicare program.

Flexibility in Medicare Advantage Uniformity Requirements (p. 56360)

CMS proposes to allow plan sponsors to offer differences in benefits tied to specific health conditions through a "new interpretation of the uniformity requirement" which will "permit MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria." (p. 56360)

CMS states "[a]s MA plans consider this new flexibility in meeting the uniformity requirement, they must be mindful of ensuring compliance with non-discrimination responsibilities and obligations" (p. 56360) CMS "will be concerned about potential discrimination if an MA plan is targeting cost sharing reductions and additional supplemental benefits for a large number of disease conditions, while excluding other higher-cost conditions. We will review benefit designs to make sure that the overall impact is non-discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations." (p. 56360)

[5]For further discussion of MA payment issues and studies concerning the experience of sicker beneficiaries in MA plans, see, e.g., the following, including citations therein: Center Weekly Alert, "CMS Releases Final 2018 Call Letter: Too Little for Consumers" April 12, 2017 http://www.medicareadvocacy.org/cms-releases-final-2018-call-letter-too-little-for-consumers/; and Center Comments on Medicare Advantage and Part D "Transformation Ideas" April 25, 2017, available at: http://www.medicareadvocacy.org/center-comments-on-medicare-advantage-and-part-d-transformation-ideas/.

This proposal, which could dramatically increase the range of benefits and cost-sharing between plans, risks allowing some MA plans to devise discriminatory plan designs, intentionally or otherwise. Such flexibility begs the question whether CMS will have the capacity to adequately review plan benefit packages for discriminatory designs (as noted in the preamble, CMS believes this proposal loosening uniformity will make assessment of meaningful differences between plans impracticable). In a climate of reducing regulatory burden for plans, will CMS invest the resources, and have adequate follow through to police discrimination as promised?

As CMS notes in the preamble, CMS began to test value-based insurance design (VBID) through the Centers for Medicare and Medicaid Innovation (CMMI) beginning in January 2017. The demo is limited by condition, geography and plan and incorporates significant consumer protections. By proposing to loosen uniformity standards for all plans, CMS is putting the proverbial cart before the horse by scaling up an experiment before we have meaningful results, including whether such flexibility – even for a much smaller cohort with specific conditions – improves health outcomes. CMS' proposal is premature in that there is not yet actionable, long-term feedback or lessons from the VBID demo as to whether altering benefits and cost-sharing in this manner is effective among the MA population – a crucial first step before significantly altering plan requirements.

Loosening uniformity requirements in the manner CMS proposes could – by itself – create a chaotic environment for Medicare beneficiaries trying to make informed decisions about what options might be best for themselves. To do so without issuing strong guard rails in the form of consumer protections and more firm restrictions on plans is a stark departure from the more thoughtful and cautious approach recently taken by CMS in rolling out the VBID demo.

When CMMI first proposed a VBID demo, the Center and other consumer advocates provided extensive feedback.[6] The resulting demonstration model reflects CMS' careful consideration of many important beneficiary protections. Such protections, or guard rails, included strong and clear parameters for program design, including: a multi-stakeholder and transparent process for identifying high-value services and developing conditions of participation; permitting only cost-sharing reductions; limiting or prohibiting advertising and other pre-enrollment marketing of cost sharing adjustments; and opt-in beneficiary selection. Here, CMS proposes to allow alteration of benefits and cost-sharing without regard to the extensive consumer protections included in the limited VBID demo.

The Center is opposed to this proposal. As discussed below, should CMS choose to proceed though, it must, at a minimum, include basic consumer protections and oversight included in the

[6] See CMA Comments re: Medicare Advantage (MA) Value-Based Insurance Design (VBID) Model September 17, 2015 available at: http://www.medicareadvocacy.org/cma-comments-re-medicare-advantage-ma-value-based-insurance-design-vbid-model/.

VBID demo. We note that none of these protections or oversight requirements are addressed, contemplated or hinted at in the proposed rule.

Consumer Protections/Oversight Recommended for VBID

The following are excerpts of comments the Center (and others) provided to CMS concerning the VBID demo:

- Conditions of participation for plans – plans under sanction and plans with below-average star rating should not be permitted increased flexibility.
- Support for educational requirements and rigorous evaluation, monitoring, and auditing schemes outlined in the announcement of the demo.
- Utilization of only positive reinforcement in the form of lowered cost-sharing and expanded benefits, rather than discouragement of lower-value services (in other words, "carrots" v. "sticks").
- Any rewards of intelligently structured insurance, including "encourag[ing] patients to consume high-value clinical services, thereby improving quality and reducing costs" should, to the extent possible, be applicable to all Medicare beneficiaries, regardless of how they choose to access their benefits. Lowering or eliminating cost-sharing in traditional Medicare, as well as offering some of the other positive incentives outlined in the VBID proposal, could also benefit the majority of beneficiaries who choose to remain in Traditional Medicare.
- Make the rationale for identifying "high-value" care publicly available. While we appreciate that CMS will be vetting plan criteria for identifying high-value services, we urge CMS to make this rationale publicly available, either as part of the demonstration or along with the evaluation of the demonstration. We appreciate that VBID has the potential to enhance health care transparency—both for cost and quality. As demonstrated by the literature, diminished cost-sharing through VBID also has the potential to improve adherence and health care outcomes, particularly among lower-income, vulnerable populations.
- Limit approval of lower cost-sharing only to instances where there is a well-established evidence-base that illustrates a particular service, prescription medication, or health care provider is in fact "high-value." We also encourage CMS to develop a standardized list of health care services or prescription drugs that may be subject to altered cost-sharing in consultation with clinicians and other experts.
- Ensure that VBID models do not benefit only geographic, economic, or other subsets of MA enrollees.
- Evaluation and monitoring- enrollee protections, like marketing prohibitions, are ineffective and without force unless compliance is monitored and enforced. For this reason, we are pleased that CMS will use "secret shoppers" to help ensure compliance with the model's marketing protections. We also support the proposed auditing

procedures and the customized scripts for 1-800-MEDICARE; CMS' audit results be made public and that diverse stakeholders are engaged and included in the process of developing the 1-800-MEDICARE call scripts. In addition, we appreciate the ongoing monitoring of plan data for coding intensity, enrollee outcomes, enrollee satisfaction, and other factors, and we would recommend that the incoming data, as well as any results or actions that result from the monitoring, be made transparent and publicly available; we recommend that MA VBID program enrollees receive clear communication from CMS on their right to file grievances and appeals and that the model's data collection include information regarding enrollee grievances and appeals.

- Disallowed marketing to beneficiaries - we strongly support CMS' approach to limiting plan marketing as outlined in the program announcement. We applaud the agency for its focus on the potential for enrollee confusion and we appreciate the steps proposed to minimize such confusion. Specifically, we endorse the prohibition on the marketing of any VBID program to beneficiaries not currently enrolled in a participating MA plan; we believe this prohibition reduces the potential for "cherry picking" of prospective plan enrollees and other potentially discriminatory practices. In addition, this prohibition ensures that individuals attracted to a VBID program who are not ultimately eligible (because they do not have the requisite health condition(s) or do not need certain services associated with the VBID program) do not end up enrolled in an MA plan that otherwise might not be the best choice for them; we also support permitting participating MA plans to convey information about VBID benefits only after a potential enrollee specifically inquires about them and only after the provision of a CMS-standard written disclaimer concerning the program and potential eligibility. Further, we encourage CMS to require prior review and approval of all written materials, including scripts for oral communication and distribution plans for materials concerning VBID benefits.
- Beneficiary and provider education and outreach - develop uniform beneficiary communications and revisit minimum requirements. We appreciate the minimum requirements for beneficiary communication included in the program design, but we are concerned these requirements fall short of ensuring full understanding among MA enrollees who might access VBID benefits. Like CMS, we do not believe the VBID model will be successful if MA plans adhere only to the minimum requirements outlined by CMS; To promote beneficiary understanding and choice, we encourage CMS to modify the proposed requirements. First and foremost, we suggest that CMS develop and require the use of standardized templates for use by participating MA plans in the VBID demonstration. At a minimum, CMS should require that all enrollee communications include plain language information about options, rights, and services in the VBID program. These communications should also direct enrollees to 1-800 MEDICARE and State Health Insurance Assistance Programs (SHIPS) that can help enrollees navigate any confusion or problems with access to care; In addition, we suggest that CMS ensure all enrollee communications are fully accessible to enrollees and their caregivers. We

suggest robust enrollee testing as well as formatting requirements. In recent CMS demonstrations, such as the Financial Alignment Initiative for dually eligible beneficiaries, we have seen first-hand the importance of beneficiary testing of notices and materials prior distribution.

- Establish a clear strategy and requirements for health care provider education and outreach. We are concerned about the lack of detail included in the program announcement with regard to provider education. From an enrollee perspective, adequate provider education is just as important as enrollee outreach for ensuring a smooth programmatic rollout. We do not believe that cost-sharing alone is an appropriate trigger to steer beneficiary utilization. Medicare beneficiaries participate in a complex health care system, within which health care providers largely direct treatment decisions. For the proposed VBID model to be successful, it must include complementary educational initiatives for both beneficiaries and health care providers. This requires targeted provider outreach that both explains the purpose of the VBID model, as well as addresses providers' practical concerns. The VBID announcement does not include detailed information for or direction to participating plans about provider education, nor does it define CMS' role in provider outreach. We suggest that provider outreach focus on contracting details and include a clear explanation of any new billing practices and procedures. We urge CMS to consider outreach to all Medicare providers who may interact with enrollees in the new VBID model. Recent demonstrations underscore the importance of ensuring community-based service providers receive outreach and training about new health care systems, as these providers are often the trusted entities beneficiaries turn to with questions.

Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (p. 56363)

CMS proposes to eliminate the meaningful difference requirement for MA plan sponsors wishing to offer more than one plan in a given service area. CMS notes that "[t]his proposal aims to improve competition, innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored to their unique health care needs and financial situation." (p. 56363) CMS notes that it "expects" plan sponsors to continue to offer plans that are "different from one another with respect to key benefit design characteristics, so that any potential beneficiary confusion is minimized…" The Center is concerned that CMS expects plans to continue with a requirement that CMS is eliminating. We believe this requirement is essential and that CMS should maintain the meaningful difference standard.

CMS outlines what it "believes" are challenges "to apply the current standardized meaningful difference evaluation … in a manner that accommodates and evaluates important considerations objectively" leading to "unintended consequences related to innovative benefit designs." Accordingly, CMS expresses a "concern" without example, quantification or other justification,

"that benefits may be decreased or cost sharing increased to satisfy meaningful difference evaluation."

CMS also notes that one of the other proposed changes in this proposed rule – loosening MA plan benefit uniformity requirements – will make meaningful difference analysis too difficult – "the current meaningful difference methodology evaluates the entire plan and does not capture differences in benefits that are tied to specific health conditions" (p. 56364)

While the preamble devotes considerable effort to explaining all of the burdens that plan sponsors must endure, CMS is correct to point out that "[r]esearch studies indicate that consumers, especially elderly consumers, may be challenged by a large number of plan choices that may: (1) Result in not making a choice, (2) create a bias to not change plans, and (3) impact MA enrollment growth."

In addition to the research cited in the proposed rule (2011 *Health Affairs* article, 2014 Kaiser Family Foundation study, cited at p. 56363), CMS previously relied on additional research to support the proposal of the meaningful difference standard. As noted by CMS in 2009, "based on several years of experience with the MA and Part D programs, we have learned that although beneficiaries need access to a variety of alternative plan options, benefit packages must represent significant differences to ensure meaningful choices" and cited to several studies that "suggest that the MA and Part D plan offerings are so numerous that they can be confusing" including the research of M. Gold (2009) and T. Rice (2008).[7] In finalizing the proposal to implement the meaningful difference requirement, CMS also cited to the work of J. Abaluck and J. Gruber (2008) as "confirming that the array of Part D plan offerings can often lead to inconsistent choices among seniors with respect to determining costs, and plan features most beneficial to them."[8]

As noted in our Overarching Comments section above, there exists a larger body of research and analysis that explores the challenges consumers face in making choices about their health insurance coverage, including when there are multitude of plan options, with little to no standardization.[9] Much of the findings in this work weigh against CMS' proposal to loosen both uniformity standards, discussed above, and meaningful difference standards.

[7] 74 FR 54670.
[8] 75 FR 1977-8.
[9] See citations in FOOTNOTE 1, above.

While CMS notes that it will maintain requirements against plans misleading beneficiaries in communication materials and will continue to review plan benefit packages to ensure that certain individuals are not discouraged from enrolling, CMS offers little evidence that beneficiaries will be better off as a result of this proposed change. Instead of relying on the large body of work concerning the challenges of consumer selection – including evidence CMS itself cites – CMS offers, as mitigation of or proposed solutions to the elimination of the meaningful difference requirement, the following: "CMS continues to explore enhancements to [Medicare Plan Finder] that will improve the customer experience […] CMS's efforts in implementing more sophisticated approaches to consumer engagement and decision-making should help beneficiaries, caregivers, and family members make informed plan choices." As an example, CMS notes a "new consumer friendly tool for the CY 2018" enrollment period "which will assist beneficiaries in choosing a plan that meets their unique and financial needs based on a set of 10 quick questions."

We remain unconvinced that such vague assertions of enhanced decision-making tools and explorations of approaches to consumer engagement will mitigate existing beneficiary challenges concerning coverage options that would be exacerbated by loosening both uniformity standards and meaningful difference requirements. Further, given CMS' stated intent to reduce plan sponsor burdens, we derive little comfort from statements pledging ongoing enforcement of other consumer protections.

"An agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." *Motor Veh. Mfrs. Ass'n v. State Farm Ins.*, 463 U.S. 29, 42 (1983). As noted above, the preamble points to research indicating that consumers can be challenged by a large number of plan choices. We agree. The record is robust in justifying the need for the initial meaningful difference policy. In this proposal to reverse course, CMS has failed to explain why previously compiled evidence and justification for this policy is now wrong, nor has CMS articulated meaningful arguments in favor of overturning this policy. We urge CMS to withdraw this proposal.

Segment Benefits Flexibility; Maximum Out-of-Pocket Limit for Medicare Parts A and B Services; Cost-Sharing Limits for Medicare Parts A and B Services

These proposals to segment benefit flexibility, add greater flexibility to plan maximum out of-pocket limits (MOOP) and allow higher cost-sharing limits for services combine to exacerbate the issues discussed above concerning barriers Medicare beneficiaries face in making informed decisions about their health insurance coverage. Allowing multiple MOOP levels and increasing the number of service categories that can have higher cost-sharing in exchange for a lower MOOP multiplies the potential variations between and among plans that will make choosing and

understanding plan benefits significantly more complex. Added to the proposals to loosen uniformity requirements and eliminate meaningful difference requirements, extensive research and comprehension will be required of anyone wishing to understand exactly what a given plan covers and how much cost-sharing applies.

CMS articulates a "goal of making sure beneficiaries can access affordable and sustainable benefit packages." While it is unclear what "sustainable" means in this context, we note that use of the term "affordable" is relative. If we interpret these proposals correctly, CMS wants to allow plans to offer higher level MOOP options for lower premiums, but with higher cost-sharing and deductibles. The MOOP is one consumer protection required of MA plans that is absent in traditional Medicare; these proposals seem to dilute this protection. Lower premiums might provide lower, ongoing monthly expense, but when a plan enrollee must use services and faces higher cost-sharing and deductibles, the notion of affordability changes.

Further, changes to plan MOOP limits can have a differential effect on beneficiaries with varying healthcare needs and costs. While individuals incurring high costs might benefit from plans that offer reduced MOOPs, beneficiaries incurring lower costs may have higher spending on services in plans with a reduced MOOP.

II. Other Proposed Medicare Advantage and Part D Changes

Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions (p. 56340)

We incorporate here, by reference, the comments to the CARA provisions submitted by the Medicare Rights Center. This includes: significant concern about the implementation of any restrictions on those identified as "potentially at-risk", and corresponding limitations on their special enrollment period (SEP) rights and lack of formal appeal rights; support for CMS' proposal to limit the category of "frequently abused drugs" to opioids for the purposes of Part D drug management programs; support for exempting recipients of hospice care, residents of certain long-term care facilities, and individuals with a cancer diagnosis, with the suggested addition of individuals receiving palliative and end-of-life care; support for disallowing sponsors to lock-in non-network prescribers or pharmacies, with the suggestion that CMS establish a threshold to determine reasonable provider and pharmacy access standards; and opposition to using the current Part D appeals process for appeals of at-risk status or other consequences of drug management.

Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (p. 56365)

Seamless Conversion Enrollment

We recognize that the MA seamless conversion/enrollment process is authorized by statute. When the Center began to hear from Medicare beneficiaries who were negatively impacted by seamless conversion enrollments, we joined other advocacy groups in raising concerns about this process that can lead to beneficiaries being enrolled in MA plans without their knowledge or consent.[10] We appreciate CMS' attention to the matter, including engaging beneficiary advocates in soliciting feedback and imposing a moratorium on approvals of new plan requests in October 2016 pending issuance of new guidance.

Absent using Secretarial discretion to rescind implementation of seamless conversion enrollment altogether, we appreciate and support CMS' proposal to significantly limit the scope of this default enrollment process. CMS proposes to limit default enrollments to parent plan sponsor companies that offer D-SNPs and Medicaid managed care plans to automatically enroll Medicaid members into the D-SNP when they become Medicare-eligible. Plan sponsors would be required to obtain both CMS and state approval for such default enrollment.

We appreciate that the current proposal significantly narrows default enrollment from the broader parameters originally permitted for seamless enrollment. We believe that the protections that CMS is putting in place are important, including the requirement for state participation and approval and for plans to be able to identify and contact beneficiaries at least 90 days prior to enrollment. The 60 day requirement is important not only to give beneficiaries adequate notice but also because, if an individual has been enrolled in a Medicaid plan for less than 90 days, it is unlikely that he has established any strong relationship with the plan and its providers and thus there would be little rationale for the default enrollment.

To ensure that the enrollment meets beneficiary needs, we urge the following additional protections:

- Enrollment should be limited to plans that have demonstrated commitment to quality, a factor that CMS noted as important in its discussion of passive enrollment.[11] We believe default enrollment should only be allowed into a SNP that has a star rating of at least three and a half stars and that has not received a civil monetary penalty or an intermediate sanction within the prior 18 months.

[10] See the Center for Medicare Advocacy's Weekly Alert, "Case Study: Enrolled in a Medicare Advantage Plan Without Her Knowledge Through Seamless Conversion Enrollment" (June 1, 2016), available at: http://www.medicareadvocacy.org/case-study-enrolled-in-a-medicare-advantage-plan-without-her-knowledge-through-seamless-conversion-enrollment/; also see Joint Advocates letter to CMS (September 30, 2016), available at: http://www.medicareadvocacy.org/wp-content/uploads/2016/10/CMS-Letter-Seamless-Conversion-093016.pdf.
[11] 82 Fed. Reg. at 56370.

- The D-SNP provider network should be substantially identical to the network in the Medicaid plan.
- Plans should be required to provide transition coverage for providers that are not in the SNP network. Transition coverage provisions in the Medicare-Medicaid financial alignment demonstration contracts provide models, and at a minimum should allow for a beneficiary to maintain an out-of-network provider for twelve months.
- Beneficiaries should have an opportunity to disenroll from the SNP to which they were enrolled by default at any time.
- Default enrollment should not be permitted in service areas where financial alignment demonstrations are taking place.
- We ask for clarification as to whether and when individuals who had ESRD while in a Medicaid managed care plan will be subject to default enrollment.[12]

CMS is also considering proposing regulations to limit the use of default enrollment to only the aged population; CMS rightly points out "concerns about disparate treatment among newly eligible individuals based on their reason for obtaining Medicare entitlement" (p 56368) – in other words, individuals with disabilities and/or ESRD. While we would like to see default enrollment eliminated altogether, this proposal to limit it to the aged would be discriminatory on its face. If default enrollment for dual eligibles is perceived to be of benefit to the individual, then it should be a benefit available to all who are similarly situated – in this instance, eligibility for Medicare.

Seamless Continuation of Coverage

While, on the one hand, CMS is proposing to limit seamless conversion enrollment, on the other hand, CMS is proposing to provide more flexibility for seamless continuation of coverage via a new "simplified positive (opt-in) election process" for enrollments of commercial, Medicaid or other non-Medicare plan members (p. 56367. This "mechanism would allow for a less burdensome process for MA organizations" (p. 56367) and would allow a longer time period for plans to accept enrollment requests (throughout Part B ICEP). However, CMS offers very few details about this proposed process and associated beneficiary protections. We note that the tight timeframe for developing details on the many changes proposed in this rulemaking, including this provision, severely limits the opportunity for a meaningful stakeholder process.

[12] Note that such individuals are permitted to elect to join a Medicare Advantage plan offered by the same plan sponsor. Medicare Managed Care Manual, Ch. 2 at 20.2.2, available at https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/CY_2018_MA_Enrollment_and_Disenrollment_Guidance_6-15-17.pdf.

CMS does, however, correctly note that "there may be significant differences between an organization's commercial plans … and its MA plans in terms of provider networks, drug formularies, costs and benefit structures" (p.56368). At a bare minimum, plan sponsors should be required to provide adequate notice concerning such changes prior to soliciting and processing seamless continuation of coverage enrollments.

More importantly, default seamless conversion from commercial plans into MA products could apply to so many new beneficiaries that it would threaten the basic clear statutory intent of Section 1851(a) that traditional Medicare be the default enrollment for individuals who do not choose. A broad exception for seamless conversion could easily undermine this core principle.

Passive Enrollment Flexibilities To Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (p. 56369)

CMS is proposing to expand passive enrollment to situations where "passive enrollment will promote integrated care and continuity of care for a full benefit dual eligible" who is currently enrolled in a D-SNP. Proposed 42 CFR 422.60(g)(iii). CMS envisions that this proposal would apply primarily to individuals in D-SNPs with associated Medicaid managed care plans operated by the same sponsor when 1) the Medicaid managed care plan is no longer contracted with the state or 2) the D-SNP no longer is contracted with CMS. Under the proposal, these individuals would be subject to passive enrollment to a new D-SNP operated by the same sponsor as the Medicaid managed care plan to which the state has assigned the beneficiary.

We appreciate that the goal of this proposal is to provide continuity to dual eligibles affected by contract changes. We also recognize, as CMS has noted, that the number of affected individuals in any year is likely to be relatively small. CMS estimates roughly 22,000 beneficiaries, small relative to the total dual eligible population, but still a significant number.[13]

We have concerns, however, about the procedure as currently proposed. First, as we have often expressed to CMS, we believe that the best way to empower beneficiaries is through mechanisms where beneficiaries opt in, rather than passive enrollment. If a beneficiary needs to leave a D-SNP because it does not match the member's Medicaid managed care plan, there are many choices that might be best for that individual, which range from traditional Medicare to PACE. CMS should ensure that affected beneficiaries have access to individual counseling so they can assess their own situation and make the choice that is best for them.

If, however, CMS decides to move forward with passive enrollment, we agree with and appreciate the proposed requirement that the provider network of the new plan be substantially similar to the network of the prior plan. It also is important that prescription drug formularies be

[13] 82 Fed. Reg. at 56434.

substantially similar. Moreover, since the provider and prescription drug usage history of these beneficiaries is available, including both the Medicare and Medicaid services that they use, we ask that CMS also undertake a more person-centered "intelligent" assignment process that pairs the beneficiary to the D-SNP/Medicaid plan that best matches his or her provider network and prescription drug needs.

Because the population affected by this provision will be small and because all data on beneficiary usage is available, passive enrollment of this population offers an ideal opportunity for CMS to work with states to develop and test intelligent assignment criteria. We believe this approach is preferable to the proposal, as currently written, where assignment to a state Medicaid plan appears to be the driver to Medicare Advantage assignment. For many dual eligibles, especially those who do not use long-term services and supports, continued Medicare coverage for their prescription drugs and Medicare providers is most important. Access to particular LTSS provider networks may be most important to others. In the design of a passive reassignment program, the state and CMS should work together to ensure appropriate reassignment without automatically prioritizing the state's Medicaid reassignment decision.

As additional beneficiary protections, we ask for transition policies that allow individuals who are passively enrolled to have a period in which they can continue to see providers who are outside their new network. As has been learned from the dual eligible financial alignment demonstrations, it is important that these policies be easy for beneficiaries and providers to navigate.[14]

We further ask that only plans with three and a half stars or more be considered for passive enrollment. Plans that are merely average should not benefit from passive enrollment.

We also note that the regulation provides no detail on beneficiary communication, other than that a single notice is required. Based on experience with passive enrollment in the financial alignment demonstrations, we ask for a more robust notice process including the following steps:[15]

- At least two notices: an initial notice at least 60 days prior to enrollment explaining the beneficiary's options and asking for a response, followed by a second notice no later than 30 days before enrollment.
- Both notices should be consumer-tested and in plain language.

[14]Focus Groups, *supra* note 5, finding that beneficiaries lacked awareness of transition protections, mainly due to the complexity of the information provided upon enrollment.

[15] Id. at 37, finding that initial beneficiary materials were overwhelming, dense, and difficult to understand. In response, CMS made significant efforts to revise model notices to make them more readable and user-friendly.

- We also ask that the initial and subsequent notices identify providers and prescription drugs that the individuals used in the prior 12 months are not in the new plan. This information will assist the beneficiary both in deciding to accept the passive enrollment and in preparing for the transition.
- Since the translation or special format needs of the beneficiaries being contacted should already have been identified, the notices should be written in the language and format appropriate to the beneficiary. If the beneficiary is identified as needing language assistance but the plan is not required to translate letters into the beneficiary's language, the plan should initiate an outgoing call to offer interpretation. Letters should all also have multi-language inserts.

If notices are returned by the postal service as undeliverable and the plan is unable to contact the beneficiary, passive enrollment should not take place and the individual should be defaulted into fee for service Medicare. Beneficiaries who receive no notice of an enrollment cannot be deemed to have consented.[16]

Part D Tiering Exceptions (p. 56371)

CMS proposes to clarify requirements for how tiering exceptions are to be adjudicated and effectuated. We support this effort as we share CMS' belief that beneficiaries currently have difficulty in understanding and using tiering exceptions. We believe that the changes CMS proposes with respect to mixed tiers and to the specialty tier are sensible steps to make the tiering exception operate as intended in light of current practices in formulary tier design.

We also ask that CMS continue to do more to educate beneficiaries about the availability of the tiering exception and require plans to do more as well.

Finally, we urge CMS to consider ways to make it easier for individuals applying for a formulary exception to also apply for a tiering exception if applicable. One option, for example, would be to have a box on exception request forms that allow an individual to also ask for a tiering exception if available.

[16] RTI, "Report on Early Implementation of Demonstrations under the Financial Alignment Initiative," (October 2015), finding that beneficiary contact information was often incorrect or outdated, making it difficult or impossible to get required passive enrollment notices to beneficiaries. Available at cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/MultistateIssueBriefFAI.pdf.

Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (p. 56373)

CMS proposes to eliminate the continuous Special Enrollment Period for dual eligibles and LIS beneficiaries and, instead create a more restricted set of SEPs for LIS beneficiaries. We object to this proposal and believe that CMS can address the limited issues it has identified through other means that do not impinge on beneficiary choice.

CMS noted that fewer than 10 percent of LIS beneficiaries used the SEP in 2016 and the vast majority of that group made only one change in a year, which CMS intends to continue to allow. The agency's concern is primarily about those who make multiple changes, including the 27,000 LIS beneficiaries who changed plans three or more times. The harms that CMS identifies include interference with care coordination and health delivery, opportunities for abusive marketing, and burden on plans, particularly integrated plans.

We have questions about the statistics that CMS relies on and whether they match up with the issues the agency is raising. For example:

- CMS has not broken down the data to separate beneficiaries who moved between Part D plans from those who moved out of or between Medicare Advantage products. Based on our contacts with advocates and counselors, it is our impression that a significant portion of the moves are between Part D plans by individuals facing problems in accessing needed prescriptions. Those moves have no impact on delivery of care since they are limited to prescription drug coverage.
- Some portion of the churning by beneficiaries making multiple changes is likely attributable to at risk beneficiaries, a concern that CMS is addressing with other measures implementing the Comprehensive Addiction and Recovery Act.
- The complaints heard from plans offering integrated products should receive further scrutiny. There are many valid reasons why beneficiaries disenroll from these plans. In a significant portion of the disenrollments, beneficiaries leave the plan because they did not understand that they had been passively enrolled, and the plan provider network did not meet their needs or preferences. These generally are not cases of multiple plan changes. Some other portion of disenrollments is attributable to loss of dual status, an issue better addressed by grace periods and other remedies. Though there is a remaining sliver of other disenrollments from integrated products that are problematic, the issues involved are unique to the financial alignment demonstration and best addressed through the demonstration.[17]
- We question whether eliminating the continuous SEP would have any impact on abusive marketing to dual eligibles. Refining marketing rules and providing continuing oversight seems to us to be a more effective response to abusive behavior.

[17] See, e.g., Focus Groups, *supra* note 5, at p.12 reporting high levels of beneficiary satisfaction with plan enrollment when care coordination was delivered.

In addition, limiting the SEP may in fact interfere with efforts to encourage beneficiaries to try integrated care products. It is our experience that those who are surprised by a passive enrollment or who suddenly realize that a Medicare Advantage plan they joined does not cover their doctor tend to simply drop the plan—sometimes in a panic-- and move into original Medicare without fully reviewing the range of options available to them. With a continuing SEP, they have the opportunity to follow up their exit with a more deliberate choice, preferably with the assistance of an options counselor.[18]

For all these reasons, we believe that the problem CMS seeks to address is not as significant as the proposal suggests and the current continuous SEP, which offers a simple and generally successful safety valve for LIS beneficiaries, should be left in place. Moreover, introducing new limits at this time is especially problematic. CMS is proposing more flexibility for managed care plans, more opportunities for Part D plans to change formularies midyear, longer appeal deadlines, and more scenarios where dual eligibles can be passively enrolled. As multiple proposed changes play out, there may be unexpected twists that will affect the need of LIS beneficiaries to change plans. If CMS wants to consider limiting the continuous SEP, we believe it would be wiser to revisit the issue at a later time.

As importantly, the CMS proposal is complex and moves from a simple easy-to-communicate SEP to a complicated and confusing menu. One overarching goal of this rulemaking is simplification and flexibility. That goal should apply to beneficiaries as well as plans, but this approach, instead of simplifying the rules for beneficiaries, inserts layers of complexity. The proposed menu of SEP options, some overlapping and some not, would be difficult to communicate. We have concerns that, as a result, beneficiaries would be unable to sort through their rights to change plans and consequently believe that they have even fewer opportunities than the regulations provide.

We strongly urge CMS maintain the continuous SEP for dual eligibles and LIS beneficiaries. It is an important beneficiary protection that is simple to understand and implement. The narrow and discrete issues that have arisen with respect to duals enrollment can better be addressed by more targeted measures that do not impose limitations on the entire LIS population.

If, however, CMS moves forward with the proposal, we request that CMS amend the current language, which treats a decision to opt out of an auto enrollment, facilitated enrollment, passive enrollment, default enrollment or reassignment as using up a SEP.[19] Currently, during the Initial Enrollment Period, the Annual Election Period and other Special Enrollment Periods, CMS treats an election as "used" only after the effective date of the election has passed: "Each individual has one election per enrollment period; once an enrollment or disenrollment becomes effective, the

[18] We also note the ongoing concerns of both CMS and advocates about the large number of "choosers" who are paying premiums for above-benchmark plans, many of whom could meet their needs in a benchmark plan. These beneficiaries often are hard to reach and it would be unfortunate if any change in SEP policy would limit opportunities to encourage them to consider changing plans.

[19] 82 Fed. Reg. at 56374.

election has been used."[20] Beneficiaries may change their election as many times as they wish before the effective date. It would be unfair, inconsistent with CMS enrollment policy, and extremely confusing to apply a different standard to SEPs available to LIS beneficiaries.

Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (p. 56375)

The proposed regulations codify existing policy and methodology for determining star ratings. Given this codification of existing policy, there were only a few new proposals. Therefore, we would like to take this opportunity to state our general support for the objectives of the star ratings in accurately informing beneficiaries of true plan quality, and in monitoring and encouraging quality improvements. We agree with CMS that "The goals of the Star Ratings are to display quality information on Medicare Plan Finder for public accountability and to help beneficiaries, families and caregivers make informed choices by being able to consider a plan's quality, cost, and coverage; to incentivize quality improvement; to provide information to oversee and monitor quality; and to accurately measure and calculate scores and stars to reflect true performance" (p. 56376).

In keeping with CMS' stated aim to provide accurate information to beneficiaries in a transparent manner, we would like to express support for a specific policy that is longstanding and is being codified through these regulations regarding data integrity. The regulations propose to codify the existing policy of reducing a contract's measure rating if CMS determines that the measure data are "incomplete, inaccurate, or biased." We agree with CMS that without such ramifications, "sponsoring organizations could 'game' the Star Ratings and merely fail to submit data that illustrate poor performance" (56395). We support CMS in developing this safeguard "to protect the Star Ratings from actions that inflate performance or mask deficiencies" (56395). Without accountability and accuracy the Star Ratings system would be, at best, meaningless for beneficiaries, and dangerously misleading at worst. We appreciate this effort and urge CMS to vigorously enforce this policy and practice vigilant oversight in this area.

In an expansion of this data integrity, CMS is proposing to reduce contract's Part C or Part D appeals measures' star ratings when independent review entity (IRE) data are not complete or otherwise lack integrity. The proposal calls for a sliding scale methodology based on severity of data integrity, whereby a contract could be penalized with a 1 Star to 4 Star reduction. We strongly support this proposal.

The Center is encouraged by CMS' proposal to address the impact contract consolidation has on star ratings. As CMS indicates, as a result of contract consolidation, reported performance for the

[20] Medicare Prescription Drug Benefit Manual, Chapter 3 at Sec. 30, available at https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicarePresDrugEligEnrol/Downloads/CY_2018_PDP_Enrollment_and_Disenrollment_Guidance_6-15-17.pdf.

contract as a whole may not be representative of local geographical performance or of the number of enrollees in the entire contract. This lessens the reliability of Star Ratings as an indicator of true quality for beneficiaries.

We support the proposal as it takes a large step in helping to ensure beneficiaries are seeing the true quality of the plans they join, but we encourage further exploration of ways to make plan quality more transparent across regions.

We appreciate the thoroughness of the audit process and the willingness of CMS to impose significant sanctions and penalties when serious deficiencies are identified. However, the disconnect between the audit process and the star rating system causes confusion among both beneficiaries and advocates. As these two avenues of oversight and evaluation diverge, the star ratings system may seem or become less valuable to beneficiaries. Of particular concern is the repeated finding of the same serious deficiencies in audits, over time, many of which directly affect beneficiary access to needed drugs and services. At the same time, plan star ratings continue to rise. To address this imbalance, it is critically important that star ratings incorporate audit measures and reflect audit results in meaningful ways.

Most importantly, when CMS finds that a plan's systems post a serious threat to the health and safety of Medicare beneficiaries, that finding must have an impact on overall ratings.
The Center would like to express our concern that the section on quality measures of the regulations seem to indicate that increasing plan participation is a goal of the Star Ratings. We do not believe that the quality rating system is an appropriate mechanism in which to encourage additional enrollment in MA plans. As stated previously, the objective of the ratings is clearly to accurately reflect the quality of existing plans so that beneficiaries can select the best plan that meets their individual needs.

We would like to take this opportunity to reiterate comments we have made to CMS previously regarding adjusting Star Ratings for socioeconomic status. We would like to emphasize that we support quality ratings that accurately reflect quality of care, and reiterate our concerns about any changes to quality measurement that allows a plan's quality rating to increase without any changes in the quality of care. We are concerned that this will mask disparities in care without addressing the poor care that disadvantaged patients disproportionately receive.
We strongly support CMS in seeking to utilize the Star Rating system to encourage continuous quality improvement in the MA and Medicare Prescription Drug programs, providing oversight to ensure accuracy and transparency, and not accepting any changes to performance measurement that would lead to masking disparities and harming disadvantaged patients.

Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (p. 56407)

Clarification to "Any Willing Provider" Requirements

Currently, Part D plan sponsors must contract with any pharmacy that meets the Part D plan sponsor's standard terms and conditions for network participation. In the preamble to the proposed rule, CMS notes the agency has previously interpreted this requirement to allow standard terms and conditions to vary to accommodate different types of pharmacies, as long as similarly situated pharmacies were offered the same terms and conditions. However, CMS recognizes that this interpretation has led to pharmacies being inappropriately excluded because they did not fit squarely within a particular provider type. Therefore, CMS is clarifying in the proposed rule that "similarly situated pharmacies" are to include "any pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy." We support the application of the "any willing provider" requirement to all pharmacy business models, including those with multiple lines of business.

Definition of "Mail-Order Pharmacy" and "Retail Pharmacy"

Also in the preamble, CMS acknowledges that "unclear references to the term 'mail order' have generated confusion in the marketplace" that has in turn "contributed to complaints from pharmacies and beneficiaries regarding how Part D plan sponsors classify pharmacies for network participation, the Plan Finder, and Part D enrollee cost-sharing expectations." CMS goes on to note that "our classifications of certain types of pharmacies were never intended to limit or exclude participation of pharmacies…that do not fit these classifications" but that some plan sponsors have nevertheless interpreted current law to mean that any pharmacy—including a retail pharmacy that provides home delivery services by mail—must contract as a mail-order pharmacy in order to participate in the plan's contracted pharmacy network.

Accordingly, CMS is proposing to define a "mail-order pharmacy" as "a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing." CMS also recognizes the existing definition of "retail pharmacy" has contributed to the confusion it is currently seeking to address, and therefore proposes to redefine a "retail pharmacy" as "any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy." We support these changes, to the extent they would resolve confusion in the marketplace.

Restoration of the Medicare Advantage Open Enrollment Period (p. 56428)

CMS proposes regulatory changes to implement the "new" Open Enrollment Period (OEP) required by the 21st Century Cures Act, which replaces the Medicare Advantage Disenrollment Period (MADP) required by the Affordable Care Act. Effective 2019, for the first 3 months of the calendar year, there will be a continuous open enrollment and disenrollment period for those individuals enrolled in an MA plan. Unlike the "old OEP" which was in effect from 2007 to 2010, the "new OEP" permits changes to Part D coverage for those who, prior to the change in election during the new OEP, were enrolled in an MA plan. Therefore, during this 3-month period an MA eligible beneficiary can make a one-time change as follows: an individual enrolled in an MA-PD plan may use the new OEP to switch to: (1) Another MA-PD plan; (2) an MA-only plan; or (3) Original Medicare with or without a PDP. The new OEP would also allow an individual enrolled in an MA-only plan to switch to – (1) another MA-only plan; (2) an MA-PD plan; or (3) Original Medicare with or without a PDP. Also unsolicited marketing is prohibited by statute during this period.

We understand that this is a statutory change but it leans toward favoring MA plans and further promotes steering toward MA plans as only those who are enrolled in an MA plan have the advantage of being able to change or pick up a Part D plan. The statute provides no protection for those enrolled in traditional Medicare who may want to change their Part D plan or pick up Part D in the first place.

Given this statutory change we ask that all CMS material, including publications and websites, make it clear and that those answering the 1-800 Medicare helpline be told that beneficiaries should be advised to enroll in a PDP as close to disenrollment from the MA plan as possible to avoid going without prescription drug coverage for a period of time. For example, a beneficiary who disenrolls from an MA plan on January 31 and enrolls in a PDP on February 1 would return to traditional Medicare on February 1, but would not have drug coverage unless they concurrently enroll in a PDP.

We are pleased that the statute prohibits unsolicited marketing during this period. We are wondering how that will be enforced and where a beneficiary should report a marketing abuse.

Revisions to Timing and Method of Disclosure Requirements (p. 56431)

The Center supports the proposal to separate the mailings of the Annual Notice of Change and Evidence of Coverage. We are, however, concerned with the proposal to increase electronic delivery of important beneficiary documents. As cited in a recent Pew study, only half of older adults have broadband at home, and a third of older adults don't use the internet.[21] To encourage

[21] Pew Research Center, May 17, 2017, "Tech Adoption Climbs Among Older Adults" available at: http://www.pewinternet.org/2017/05/17/technology-use-among-seniors/.

fewer paper deliveries we would encourage CMS to allow beneficiaries to opt-in to electronic delivery. Paper delivery should still be the default method of delivery. The Center for Medicare Advocacy also incorporates by reference comments on this issue made by the Medicare Rights Center, Justice in Aging and the National Council on Aging.

Revisions to §§422 and 423 Subpart V, Communication/Marketing Materials and Activities (p. 56433)

CMS proposes to narrow the scope of what is considered "marketing materials" to exclude certain enrollee communications. CMS states "the majority of member materials would no longer fall within the definition of marketing under this proposal." The Center is concerned that CMS is reducing oversight of important plan materials and at the same time CMS is proposing to give plans more flexibility on plan design and in the types of benefits that can be offered. CMS states that through their review of thousands of marketing materials and complaints and investigations they have gained insight into the types of plan materials that present the greatest risk of misleading or confusing beneficiaries. While this may be true CMS has no insight with respect to how plan material might change given the proposed elimination of the meaningful difference requirement which could lead to varied plan designs that may be very confusing. CMS should not curtail their oversight of certain plan materials before they have gained insight with respect to how plan materials might change given the many proposals set forth that give plans increased flexibility. Specifically we would encourage CMS to treat the Evidence of Coverage and the Summary of Benefits as marketing materials as their content can be critical with respect to influencing a beneficiary's decision-making process. We would also strongly encourage CMS to undertake a program to expand the number of documents subject to the translation requirements. The Center also incorporates by reference comments made on this issue by the Medicare Rights Center, Justice in Aging and the National Council on Aging.

Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (p. 56437)

Currently both Part D plan sponsors and the independent review entity (IRE) must issue decisions within 7 days in response to enrollee standard (non-expedited) requests for plan redetermination and IRE reconsiderations with respect to payment. CMS proposes to extend the time frame for a plan to issue a decision on payment redeterminations from 7 calendar days from the date the plan sponsor receives the request to 14 calendar days from the date the plan sponsor receives the request. This would also apply to the IRE reconsideration time frame. CMS would keep existing time periods the same in cases where the enrollee did not receive the drug and is requesting that it be provided. CMS asserts that limiting the change to cases where reimbursement is sought would limit the health effects of the proposed policy. CMS notes that in cases resolved in the enrollee's favor, the plan sponsor would still be required to make

payment no later than 30 days from receipt of the request for redetermination, or the IRE reconsideration notice, respectively.

We encourage CMS to keep the existing deadline for plan sponsors and the IRE as we have concerns about the effect this change would have on beneficiaries. CMS agrees that "some enrollees would have to wait longer for a decision" but justifies this by noting that the change is limited to a payment request where the enrollee has already received the drug "ensuring any delay would not adversely affect the enrollee's health." The proposed policy would add another 14 days to denials that are appealed to the IRE. Part D drugs can be very expensive and the majority of Medicare beneficiaries have limited income and savings. The Center recently assisted a beneficiary who was prescribed a drug to treat metastasized lung cancer that costs $12,000 a month. It is conceivable that a beneficiary who requires a Part D drug will have to continue paying out of pocket for it while waiting for a decision on the appeal, especially if it is a critical or potentially live saving medication. An enrollee with a limited budget may be forced to forego making further purchases of the same drug as they await a decision, which could absolutely have an adverse effect on their health. It is also conceivable that a beneficiary, while waiting for a redetermination or IRE reconsideration, may still have to pay for the Part D drug that is the subject of the appeal and may use the information from the decision(s) to make an informed consumer decision whether they will need to plan to pay for the drug out of pocket again or get a prescription for an alternative drug.

Furthermore, CMS justifies this change by citing to greater consistency in Part D coverage and appeals processes as § 423.568(c) requires a plan sponsor to notify the enrollee of its determination no later than 14 calendar days after receipt of the request for payment. CMS believes that giving more time to adjudicate payment redetermination requests will ease the burden on the plan sponsor because it could reduce the need to deny payment redeterminations due to missing information. One has to ask how it is possible that there could be that much, if any, missing information at this level of review. The MA plan makes the decision at both the first level of review as well as the redetermination level. One would hope that the decision at the first level of review was "fully informed." By the time the case gets to the redetermination level of review there should not be much, if any, missing information. The MA plan has already been given 14 days for the first review to gather information and then currently has another 7 days at the next level. That should be sufficient time to gather any additional necessary information.

Finally, these changes are being proposed under the guise that the 7-day time frame to make a decision is a burden on the plan sponsors and the IRE. Gathering documentation and making a fully informed decision within 7 days should not be characterized as a burden. Plan sponsors are private companies that contract with Medicare and have legal responsibilities to meet the deadlines as set forth in the Medicare regulations. Plan sponsors and providers are the keepers and holders of all of the information needed to make a decision and are well suited to get the required information to make a fully informed decision in a timely manner. The beneficiary should not be punished with longer wait times to justify giving plan sponsors and the IRE more

time to do what they are contractually required to do and capable of doing especially given the fact that longer wait times could have an impact on an enrollee's decision on how they will receive and pay for necessary care.

Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE (p. 56438)

In this section CMS proposes to eliminate the requirement that MA plans notify an enrollee when a reconsideration decision is deemed adverse or partially adverse to the enrollee and has been referred to the independent review entity (IRE). The rationale for this is that the plan notice is duplicative and nonessential because the Part C IRE is contractually responsible for notifying an enrollee that the IRE has received and will review the case. CMS believes it will ease the burden on the MA plan without compromising information given to the beneficiary of the progress of their appeal.

We agree that giving two notices is duplicative and probably not necessary. We also agree that eliminating the plan notice will not compromise the information given but it will absolutely compromise the timing of the information given. It is conceivable that a beneficiary may still be receiving a course of services that are the subject of the denial and may use information from the plan's model notice to make an informed consumer decision whether to continue receiving the services. The regulations as currently written require the plan to concurrently notify the enrollee of their action referring the matter to the IRE. While it is not clear what the contractual responsibility of the Part C IRE is for notifying an enrollee that they received the case, that notification would most certainly not be as timely as a notification from the plan. Therefore, if the true intent is not to compromise informing the beneficiary of their appeal then the IRE notice should be eliminated, not the plan's notice. Enrollees should continue to be informed of the disposition of their appeal as soon as possible and we strongly recommend that the requirement that the MA plans notify the beneficiary not be removed.

Furthermore, it doesn't seem like the burden here is substantial enough to delete this important protection in the regulations and rely instead on a contractual responsibility. CMS even admits that they made a model notice available for plans to use to notify the enrollee that the plan has upheld its decision and is forwarding the case file on to the IRE. It cannot be that burdensome to send off a model notice designed for that specific situation. Finally, many, if not most, plan enrollees likely have no idea what an IRE is or what the name of the IRE contracting with their plan is and would therefore likely not recognize a letter from the IRE. A plan enrollee is much more likely to recognize, open and pay attention to a letter from their MA plan. Therefore, in order to ensure that an enrollee recognizes and opens the notice it makes more sense for the enrollee to receive a letter from their plan letting them know to expect a letter from the IRE.

Preclusion List

Part D Provisions (56441)

CMS proposes to delete the current regulation that requires prescribers to enroll in or opt out of Medicare for a pharmacy claim (or beneficiary requests for reimbursement) for a Part D drug prescribed by a physician or eligible professional to be covered. CMS's rationale for this was that "forging a closer link between Medicare's coverage of Part D drugs and the provider enrollment process would enable CMS to confirm the qualifications of the prescribers of such drugs." (p. 56441). CMS pointed out that although numerous prescribers have either enrolled in or opted out of Medicare, as of July 2016 approximately 420,000 prescribers whose prescriptions for Part D drugs would be affected by the requirements have yet to enroll or opt out. Provider organizations expressed that the burden of these requirements outweighed the payment safeguard benefits. CMS proposes to replace the enrollment requirement with a preclusion list that would prevent Part D coverage of prescriptions written by prescribers who pose an elevated risk to Medicare beneficiaries and the Trust Funds. The process that CMS envisions and proposes involves a 3 step process which would result in the compilation of a preclusion list.

The Center is concerned that the "preclusion list" will not protect Medicare beneficiaries as well as requiring that all prescribers be enrolled in Medicare. Instead of making sure that each prescriber is enrolled in Medicare so that CMS can make sure that, in their own words, "Part D drugs are prescribed only by qualified prescribers" CMS is relying on a risk-based approach so that it is only after a prescriber has already engaged in inappropriate activities that they are put on the preclusion list. The process of applying for enrollment and subsequent enrollment allows CMS to investigate and curtail problematic prescribe enrollments before they occur. This proactive approach would create the most secure atmosphere for beneficiary safety and wellbeing while protecting the Medicare program from the fraud and abuse identified by CMS as the prime driver of the previous requirement. Reactive provisions such as a preclusion list must by their very nature lag behind proactive provisions such as enrollment requirements. CMS proposes to assess providers based on the risk to Medicare beneficiaries and only focus on those who pose an elevated risk, but identifying those who pose an elevated risk is the very purpose of an enrollment process. CMS' proposal, then, may put beneficiaries at risk for inappropriate prescribing practices from physicians and eligible professionals who would not have successfully completed the enrollment process.

CMS notes that after publication of the May 23, 2014 final rule they undertook major efforts to educate affected stakeholders about the enrollment requirements. This apparently resulted in approximately 65% (100% - 35% of those who remain unenrolled according to CMS's figures) of the total prescribers either enrolling or opting out. This is an impressive number. Instead of scrapping the requirements all together and relying on the complaints of those prescribers who found the process burdensome CMS should proceed with the enrollment requirements and provide additional outreach regarding the enrollment process.

Part C/Medicare Advantage Cost Plan and Pace Provisions (56447)

CMS proposes to rescind the current regulation that requires providers and suppliers that furnish health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA plan to be enrolled in Medicare and be in an approved status no later than January 1, 2019. In the proposed regulations CMS indicates that roughly 120,000 MA-only providers and suppliers remain unenrolled in Medicare and points out that MA plans have raised concerns over the enrollment requirement and the burden involved in enrolling in Medicare. CMS seems to agree with this burden argument and the fact that beneficiaries could lose access to needed providers when the full enforcement of the enrollment requirement begins on January 1, 2019. CMS proposes to replace these provisions with a requirement that MA plans reject an item or service if a specific provider is on a "preclusion list." These "preclusion lists" would include providers who are currently revoked from the Medicare program or under an active reenrollment bar or have engaged in behavior that is not in the bests interests of the Medicare program.

For several reasons, we would strongly encourage CMS not to eliminate the requirement that providers be enrolled in Medicare as of January 1, 2019. CMS admits "we maintain that Medicare enrollment, in conjunction with MA credentialing, is the most thorough means of confirming a provider's compliance with Medicare requirements and of verifying the provider's qualifications to furnish services and items…." (p. 56448). CMS set out their reasoning for adding enrollment requirements which included 1) ensuring that Medicare enrollees receive items or services from providers and suppliers that are fully compliant with the requirements for Medicare enrollment; 2) assisting in efforts to prevent fraud, waste, and abuse and to protect Medicare enrollees by allowing CMS to carefully screen all providers and suppliers to confirm that they were qualified to furnish Medicare items and services; 3) requiring Medicare enrollment in addition to the existing MA credentialing requirements permits "a closer review" of MA providers and suppliers; and 4) the fact that CMS has access to information and data not available to MA organizations. CMS should keep those requirements in place and step up outreach to those who could have enrolled but have not. This proactive, not reactive, process is the superior option for protecting beneficiaries and the Trust Funds.

There are also continuity and access to care issues that are not being considered or addressed by CMS. The choice of Medicare options has serious consequences for access to services and physicians and it is important that the impact on beneficiaries be considered. Not requiring MA providers to be enrolled in Medicare is particularly problematic for MA enrolled beneficiaries who are patients of a provider not enrolled in Medicare who disenroll from the MA plan and elect traditional Medicare. Those beneficiaries would no longer be able to receive services and have them billed to Medicare. An advocate at the Center for Medicare Advocacy assisted a

beneficiary who had been seeing a specialist for many years while enrolled in an MA plan. Once the beneficiary returned to traditional Medicare, he no longer had access to his specialist because they were not enrolled in Medicare. The beneficiary had developed a long-standing relationship with the doctor who had performed his pervious surgeries and understandably wanted to continue receiving care from that particular doctor. In order to continue seeing the specialist the beneficiary was forced to pay out of pocket. The specialist had "opted out" of Medicare and therefore the beneficiary was unable to have the services paid by Medicare. The beneficiary paid thousands of dollars out of pocket to continue seeing their doctor.

In the event that CMS removes the enrollment requirement, which we strongly oppose, we would ask that some protection be put in place so that a beneficiary, like in the above scenario, who disenrolls from an MA plan can continue to see a provider who did not enroll in Medicare and that the provider can be allowed to submit a claim to Medicare on behalf of the beneficiary. Conversely, should CMS choose to retain the enrollment requirement, we urge CMS to allow some flexibility for MA coverage of services of providers who are highly specialized and do not typically accept Medicare.

CMS also asks for comment regarding whether additional beneficiary protections, such as notices to enrollees when an individual or entity that has recently furnished services or items to the enrollee is placed on the preclusion list or a limited and temporary coverage approval when an individual or entity is first placed on the preclusion list but is in the middle of a course of previously covered treatment, should also be included in the rules upon finalization. We would strongly encourage CMS to consider including notice requirements so that all individuals receiving care or treatment from an individual or entity placed on the preclusion list be notified well enough in advance so that they can seek care and treatment elsewhere. We would also ask that an exception be made for those in the middle of a course of previously covered treatment so that their care is not interrupted.

"An agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." *Motor Veh. Mfrs. Ass'n v. State Farm Ins.*, 463 U.S. 29, 42 (1983). As noted above, CMS gives adequate, and non-exhaustive reasons, why all applicable Part D prescribers and MA providers and suppliers should be enrolled in Medicare. We agree with all of the reasoning. The reasons supporting the need for Medicare enrollment are clear. In the proposals to reverse course for both Part D and Part C enrollment, CMS has failed to explain why previous justifications for the regulations are now wrong, nor has CMS articulated meaningful arguments in favor of overturning the current policies in place. We urge CMS to withdraw the proposals to eliminate enrollment requirements and to replace current requirements with a single preclusion list that includes all affected individuals and entities.

Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements (p. 56456)

The Affordable Care Act imposed a requirement that most Medicare Advantage plans have to meet a minimum Medical Loss Ratio (MLR) of 85 percent. A plan's MLR reflects the percentage of premium dollars that are spent on clinical services and activities to improve health care quality (quality improvement activities, or QIA). MLR requirements, therefore, limit the amount that a Medicare Advantage plan can spend on marketing, CEO salaries, profits, and other administrative costs. In general, the higher a plan's MLR, the more value the consumer is getting.

When CMS originally promulgated regulations around the MLR, it recognized that allowing an unlimited adjustment for fraud reduction expenses would undermine the purpose of requiring issuers to meet the MLR standard. Now CMS proposes to permit all fraud prevention activities to be included as QIA. The Center considers the original CMS position more persuasive and sees the proposed change as undermining the purpose of the MLR. The MLR should reflect monies spent on health care quality just as it does in commercial and Medicaid rules. It should not reflect administrative costs such as fraud prevention.

Conclusion

We appreciate the opportunity to submit these comments. If you have any questions or need additional information, please contact David Lipschutz, Senior Policy Attorney, at dlipschutz@medicareadvocacy.org, or 202-293-5760.

Sincerely,

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