JUSTICE IN AGING

FIGHTING SENIOR POVERTY THROUGH LAW

January 16, 2018

By electronic delivery to www.regulations.gov

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

Justice in Aging appreciates the opportunity to provide comments on the above-referenced Notice of Proposed Rulemaking (NPRM).

Justice in Aging is an advocacy organization with the mission of improving the lives of low-income older adults. We use the power of law to fight senior poverty by securing access to affordable health care, economic security and the courts for older adults with limited resources. We have decades of experience with Medicare and Medicaid, with a focus on the needs of low-income beneficiaries and populations that have traditionally lacked legal protection such as women, people of color, LGBT individuals, and people with limited English proficiency.

We appreciate the opportunity to comment on the extensive changes proposed in this rulemaking. We have organized our comments by beginning with some general comments that cut across specific provisions but focus primarily benefit design and beneficiary protections. We then offer specific comments on those sections that most impact the low-income older adults for whom we advocate.

A. Overall Comments

This NPRM proposes a wide range of significant changes to the way that the Medicare Part C and Part D programs operate. Many of the changes would give plans more flexibility, fewer requirements, and less oversight. CMS asserts that the changes will promote innovation and improve efficiency.

We have supported and continue to support refinement of the Part C and D programs when those refinements provide additional transparency for beneficiaries and make the programs easier to navigate and understand. We also support changes that offer more robust benefits, support the goals of living safely in the community, and offer opportunities for better health outcomes.[1] Having worked with both

[1] We have appreciated, for example, improvements in beneficiary notices, improvements in the Best Available Evidence policy, secret shopper surveys of plan consumer assistance telephone services, closer monitoring of the accuracy of plan provider directories, extension of nursing facility level LIS co-insurance to individuals receiving LTSS in the community, the VBID demonstration, the technical assistance that CMS has provided to plans on their obligations to QMB members, and many other steps by CMS to improve program performance and protect beneficiaries.

WASHINGTON
1444 Eye Street, NW, Suite 1100
Washington, DC 20005
202-289-6976

LOS ANGELES
3660 Wilshire Boulevard, Suite 718
Los Angeles, CA 90010
213-639-0930

OAKLAND
1330 Broadway, Suite 525
Oakland, CA 94612
510-663-1055

programs since their inception, we have seen that, whenever changes are introduced, challenges arise that are more complex than originally anticipated. Strong beneficiary protections and responsive assistance mechanisms need to be in place to address individual and systemic issues that arise. Experience also has shown that vigorous CMS oversight of plan actions is an essential element in maintaining and improving quality.

We appreciate that some of the changes in the proposed regulations support these goals and address issues that beneficiaries have faced in the programs. We have serious concerns, however, that some proposed changes, either in part or in their entirely, do not. To summarize our major concerns:

Scope and Timing. The scope of the proposal is remarkably broad. It proposes changes to the Medicare program that would allow plans to offer supplemental benefits for only specific groups of beneficiaries, to offer segmented benefits, and to have more leeway in designing Part C and D benefit packages. Further, CMS proposes to offer both Part C and D plans opportunities to limit mailings of information to beneficiaries, submit fewer documents to CMS for review, change formularies midyear without notice, take longer to delay or slow down appeals, and make other changes that could profoundly affect the lives of older adults and people with disabilities who rely on Medicare. Most of these changes are expected to be available to plans for the 2019 plan year, though implementation details generally have not yet been offered for comment, or, to our knowledge, finalized.

Simply put, we believe that what is proposed is too much too fast. In many ways, the large changes proposed in the NPRM are national demonstrations, often overlapping, and immediately enshrined in regulation, without the protections and rigorous evaluations that typically characterize CMS demonstrations. With so many changes, it will be hard to evaluate which change is responsible for which outcome.

Implementing so many changes so fast to an already complex system will present serious challenges to beneficiaries. Some challenges we can predict, like the lack of tools for beneficiaries to sort out their coverage options. Other unforeseen challenges are very likely, particularly since many of the changes will cascade, one upon the other. One clear lesson that both advocates and CMS have learned through the development and maturation of the Part C and Part D benefits is that even small changes generate unanticipated challenges. The changes proposed in these regulations are not small. As discussed in more detail in our specific comments, we strongly urge CMS to test these proposals before revising regulations and to phase in changes so that the impact of particular actions on beneficiaries and on outcomes can be identified and analyzed.

Transparency and Beneficiary Enrollment Choices. Current proposals to add flexibility for plans will add complication for beneficiaries. CMS is proposing to eliminate the meaningful difference requirement for plan offerings in both Medicare Advantage and Part D and to give plans much more leeway in plan benefit design. In 2018, beneficiaries already have an average of 21 choices among Medicare Advantage plans[2] and 23 Medicare Part D plans.[3] As CMS has noted, studies show that many beneficiaries already feel overwhelmed and report that they find themselves unable to make a choice.

[2] *See* Kaiser Family Foundation, Medicare Advantage 2018 Spotlight, *available at* www.kff.org/medicare/issue-brief/medicare-advantage-2018-data-spotlight-first-look/.
[3] *See* Kaiser Family Foundation, Medicare Part D, A First Look at Prescription Drug Plans in 2018, *available at* www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2018/.

In proposing these changes, CMS has expressed confidence that improvements in the Plan Finder, the only tool for plan comparison, will help beneficiaries navigate the new complexities. We appreciate that CMS is developing Plan Finder enhancements and ask that they be thoroughly tested with State Health Insurance Assistance Programs (SHIPs) and beneficiaries. We urge CMS to ensure that those enhancements come first, before any rule changes are implemented and before beneficiaries are confronted with even more difficult choices. Beneficiary choice is meaningless if beneficiaries do not have the tools to reasonably exercise that choice.

Currently the Plan Finder only allows head-to-head comparisons of plans' drug coverage and does not allow a beneficiary to search across plans for particular providers. Further the SHIP program, which offers one-on-one personalized assistance, is underfunded to meet current challenges. Continued SHIP funding, even at current levels, is under threat. 1-800-MEDICARE, while a needed resource, does not substitute for this type of in-person assistance. We urge CMS not to enact the many proposals in this rule that offer plans more flexibility, and increase complication for beneficiaries, until CMS ensures that beneficiaries have the tools to evaluate and compare their choices.

At the same time that CMS is proposing significantly more flexibility by plans, it also is proposing to eliminate the continuous Special Enrollment Period for dual eligibles and beneficiaries who qualify for the Low Income Subsidy (LIS), and replace it with a complicated set of limited special enrollment periods (SEPs). These restricted SEPs will be difficult to communicate to beneficiaries and lead to confusion about when and whether a beneficiary can change plans. Older adults and people with disabilities who qualify for LIS do not have the financial resources to weather any disruption or denial of care. When plan design becomes more complex, and beneficiaries experience passive and default enrollments, those who qualify for LIS need the protections that a continuous SEP provides. Furthermore, they need enrollment procedures that they can easily understand.

Beneficiary rights and ability to navigate their benefits. We urge CMS to reevaluate these proposed changes from the perspective of a beneficiary trying to get needed services. Once enrolled in a plan, beneficiaries need easy-to-navigate avenues to ensure access to their benefits. They need an appeal route that works and produces timely decisions. In our specific comments, we offer concerns and suggestions around appeal rights with respect to access to supplemental benefits, appeals for individuals facing restrictions based on CARA, and the timing proposals for forwarding appeals to the Independent Review Entity (IRE). We also point to areas where CMS needs to look particularly closely at how plans educate their members and ensure that all members have access to services, including especially hard to reach populations.

Beneficiaries with limited proficiency in English also need more translated notices, particularly when benefits are denied or curtailed. We appreciate that the NPRM proposes changes that would no longer limit translation requirements to marketing materials and urge the agency to undertake a comprehensive review of plans' translation obligations.

Besides formal appeal routes, beneficiaries also need help navigating their benefits. We strongly urge CMS to expand and strengthen its Medicare ombuds program. A broader ombuds program would give beneficiaries needed assistance and also allow CMS to better identify systemic issues that are likely to arise as different benefit designs are implemented.

Oversight and evaluation. Despite the very significant changes being proposed, the NPRM includes several provisions that would limit, rather than increase, the agency's oversight of plans. Plan oversight

is a core responsibility of CMS. It is an obligation that the agency owes to its beneficiaries. While we certainly support efforts to make the oversight function more efficient and less burdensome, we note that the obligation to oversee plan performance and evaluate outcomes is greater, not less, when there is increased flexibility and variety in plan design. We also note that the many improvements that CMS has made in data collection, availability, and analysis enhance the agency's ability to evaluate results. Data-driven analysis of beneficiary outcomes is critical. We are concerned that the NPRM has little discussion of reporting requirements and evaluation protocols to determine which of the changes are actually resulting in improvements for beneficiaries.

B. Specific Sections (Headings are identified using the heading numbers in the Table of Contents in the NPRM and the initial Federal Register page number.)

II.A.1(c)(2)((i)(A) Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions--Definition of "Potential At-Risk Beneficiary" and "At-Risk Beneficiary" (p. 56342)

CMS proposes definitions for two beneficiary categories: "At-Risk Beneficiaries" and "Potential At-Risk Beneficiaries." We are concerned with how CMS proposes to both define and impose limits on "Potential At-Risk Beneficiaries," defined as those who have been identified using the clinical guidelines by either the current sponsor or a previous sponsor. Beneficiaries in this category, though they have not been formally determined to be at-risk for misuse or abuse of frequently abused drugs, will be, under the proposed rules, subject to limitations on their SEP rights and will have no formal appeal rights to contest limitations imposed on them. As further discussed below, Justice in Aging objects to using LIS/dual eligible SEP restrictions as a tool to address misuse of frequently abused drugs. Limiting SEP rights for individuals who have been identified, rather than formally determined, as "potentially" at risk, is particularly concerning and should not be permitted.

II.A.1(c)(2)(i)(B) Definition of Frequently Abused Drug (p. 56343)

Justice in Aging strongly supports the CMS proposal that only opioids be included in the current category of "frequently abused drugs," and that other drugs could later be added to this category through the annual Call Letter or other guidance. Once the program is established and testing and monitoring indicates the program can be administered in a manner that does not unduly limit beneficiary access to needed medications, CMS could revisit expansion of the Part D drug management program. But it is imperative now and in any future expansions that no medications in the protected classes or medications that are vital to protecting public health (e.g., anti-retroviral medications) be subject to lock-in. Nor should any medications that treat substance abuse disorders be included in the lock-in.

We also support CMS's proposal to no longer allow plans to implement drug management on non-opioid medications. In order to best protect beneficiary access to needed medication, CMS should implement a conservative and uniform approach to medication management across all plans. This is especially important because how a plan implements such restrictions may not be readily available or transparent to potential enrollees, and informed beneficiary choice is the bedrock of Medicare.

CMS proposes to prohibit plans from voluntarily expanding the scope of potential at-risk beneficiaries than CMS identifies. As with the non-opioid limitations above, we support a clear and universal set of guidelines that will help ensure beneficiaries get the information and the medications they need with as little disruption as possible. Differing plan standards increase beneficiary confusion and fragmentation across the Medicare landscape.

We urge CMS to regularly monitor plan drug management programs, with particular vigilance against development or implementation of systems that would either inadvertently or intentionally over-select low-income beneficiaries, historically disadvantaged people of color, women, people with disabilities, or people with certain diagnoses.

II.A.1(c)(2)(i)(B) Definition of Exempted Beneficiary (p. 36346)

CMS proposes to exempt recipients of hospice care, residents of certain long-term care facilities, and individuals with a cancer diagnosis from CARA-based restrictions. We encourage CMS to also exempt individuals who are receiving palliative and end-of-life care but not enrolled in hospice. Although CMS indicates that it expects plans will not impose limits on individuals in these circumstances, we recommend an explicit exemption as the better course. Without an exemption in the regulation, beneficiaries are exposed to a potential risk of being included in the drug management program at the plan's discretion and losing access to vital pain-controlling medications when they need them most.

II.A.1(c)(2)((iv) Case Management/Clinical Contact/Prescriber Verification (p. 56348)

CMS proposes that plan sponsors "make reasonable attempts to communicate telephonically with the prescribers within a reasonable period after sending the written information" about a potentially at-risk patient. This is a less rigid standard than current CMS policy which sets a specific number of post-notification contact attempts to be made in a specific time frame. While we do not object to additional flexibility where necessary, sponsors must ensure that any records of such contacts are easily accessible to beneficiaries deemed to be at-risk who wish to appeal their designation. Those records must also be able to be easily auto-forwarded to the Independent Review Entity (IRE) as required by the statute.

II.A.1(c)(2)(vi) Requirements for Limiting Access to Coverage for Frequently Abused Drugs (p. 56349)

Justice in Aging supports the CMS proposal that sponsors must obtain prescriber agreement before implementing pharmacy lock-in. Providers are better positioned to understand and manage a beneficiary's use of frequently abused drugs. Overriding a prescriber's professional judgment should require extreme circumstances. This approach will best ensure that beneficiaries have access to needed medications.

CMS proposes that in the case of an unresponsive prescriber, sponsors may move ahead with limiting an at-risk beneficiary's access to frequently abused drugs without prescriber agreement. While we understand the need for some form of backup method in cases where prescribers are truly unavailable, we suggest that establishing a 30-day window for prescriber response is less likely to lead to avoidable disruption of needed medications.

II.A.1(c)(2)(vii) Beneficiary Notices and Limitation of Special Enrollment Period (p. 56350)

(A) Initial Notice to Beneficiary and Sponsor Intent to Implement Limitation on Access to Coverage for Frequently Abused Drugs (p. 56350)

CARA requires written notices from sponsors that intend to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs. CMS proposes to require that the initial written notice use language approved by the Secretary and be in a readable and understandable form. CMS also proposes to require more information and detail than is demanded in the statute. We support both the proposed requirements and the enhanced content. It is especially important that beneficiaries understand the full scope of the at-risk designation and what they can and cannot do as a result. The notice should include an explanation of how at-risk designations follow individuals if they change plans, which obviates any need for limitations on SEPs for at-risk or potentially at-risk individuals.

We also strongly urge CMS to designate these notices to be among those subject to the translation in proposed sections 422.2268 and 423.2268.

In addition to approving notice language, CMS should develop specific educational materials and notice templates that include the details of the program as finalized through regulation, including information about how to appeal a designation as "at-risk" and how to seek help from the plan sponsor as well as from independent sources, including 1-800-MEDICARE and SHIPs.

CMS also proposes to permit the initial notice to be used when the sponsor implements a beneficiary-specific POS claim edit for frequently abused drugs. We support this regularization and streamlining of notices.

CMS proposes an order for program requirements:

- First, case management, which encompasses clinical contact and prescriber verification and agreement;
- Second, provision of an initial notice indicating the sponsor's intent to limit the beneficiary's access to frequently abused drugs.

We support this proposed order of action by plans. It would reduce the risk of causing beneficiaries alarm and confusion if they were to receive an erroneous notice that they may face an interruption or limitation on their needed medications if, for example, they are actually exempt from the program or otherwise not an at-risk individual.

In addition, we support the two-step notice process as laid out by CMS that would require an initial notice followed by a second notice to confirm or revoke the initial notice. Having multiple notices increases the likelihood that beneficiaries will be actually notified of their status and the actions they can take to adjust or challenge that status.

(B) Limitation on the Special Enrollment Period for LIS Beneficiaries with an At-Risk Status (p. 56351)

CMS proposes to restrict the SEP for individuals who are identified as at-risk or potentially at-risk. Justice in Aging strongly disagrees with this proposal. Under statute,[4] beneficiaries who are eligible for both Medicare and Medicaid are afforded the protections of a SEP. CMS appropriately extended a continuous SEP to all LIS beneficiaries. Many low-income beneficiaries, including those at-risk, have multiple chronic conditions and complex medical and prescription drug needs. They may need to switch plans because of changes to their own medical needs, including new medications unrelated to the lock-in, or because of other changed circumstances or preferences. Nothing in CARA would override the statutory SEP protection for dual eligibles or make an at-risk or potentially at-risk dually eligible beneficiary ineligible for an SEP. CMS should not add additional "locking in" beyond that contemplated by the statute.

As CMS acknowledges in the definitions for "Potential At-Risk Beneficiary" and "At-Risk Beneficiary," CARA provides that "at-risk" status is transferable from one plan to another. This means that a lock-in would remain in place, regardless of whether an individual utilizes the SEP. Accordingly, since the SEP cannot be used to avoid the lock-in provisions, there is no policy reason to curtail it. Beneficiary education will be the most effective way to ensure that at-risk or potentially at-risk beneficiaries understand how to challenge their at-risk designation if they wish to avoid the lock-in.

(C) Second Notice to Beneficiary and Sponsor Implementation of Limitation on Access to Coverage for Frequently Abused Drugs (p. 56352)

[4] 42 U.S.C. 1395w-101(b)(3)(D).

As with the initial notice discussed above, CMS proposes to enhance the statutorily-required notice to beneficiaries who are determined to be at-risk with more information and detail on the limitations they will face as well as actions they can take to mitigate their status. CMS also proposes, as with the initial notice, that the second notice could be used when the sponsor implements a beneficiary-specific POS claim edit for frequently abused drugs. We support these additions and options.

CMS notes that current policy allows a plan sponsor to send only one notice when it implements a beneficiary-specific POS claim edit for frequently abused drugs. CMS proposes that, when the POS edit is related to an at-risk determination, it would require two notices as well as appeal rights. We support this change to ensure beneficiaries have the information about and access to protections when their access to medications is limited because of "at risk" status. We reiterate, however, that the additional "lock-in" of limiting use of the LIS SEP, which is not included in the statute, should not be included.

(D) Alternate Second Notice When Limit on Access Coverage for Frequently Abused Drugs by Sponsor Will Not Occur (p. 56353)

CMS proposes that if a sponsor provides an initial notice but does not finally decide to implement the limitation on the beneficiary's access to frequently abused drugs, that sponsor would be required to provide the beneficiary with an alternate second notice that informs the beneficiary that the sponsor no longer considers the beneficiary to be potentially at-risk and will not place the beneficiary in its drug management program. CMS states this notice is not explicitly required by the statute but is consistent with the intent of the statute and is necessary to avoid beneficiary confusion and minimize unnecessary appeals. We agree. If the beneficiary received only the initial notice, this could lead to confusion, unnecessary appeals, and, in extreme circumstances, could even discourage beneficiaries from seeking medical attention.

(E) Timing of Notices (p. 56353)

CARA requires that there be at least 30 days between an initial and second notice of a plan sponsor's intent to limit access to frequently abused drugs. CMS proposes that the second notice or alternate second notice be sent within 90 days of the initial notice. While we support having a deadline by which sponsors must provide that second or alternate second notice, 90 days is too long, given that those identified as "potentially" at-risk would have their rights limited without any form of appeal. If CMS were instead to choose not to penalize those identified as potentially at-risk, however, 90 days would be more acceptable.

CMS also proposes that in the case of an at-risk beneficiary switching to a new plan, the gaining plan will be permitted to send a second notice and implement a limitation on the beneficiary's access to frequently abused drugs either through a beneficiary-specific POS claim edit or, in the case of lock-in procedures, only if the gaining plan has the beneficiary's chosen pharmacies or prescribers in its network, as applicable. We appreciate that this proposal would limit the possibility for disruption for the beneficiary. However, beneficiaries must have a clear method to change pharmacy and/or prescriber since they may have opted to switch plans precisely in order to have access to a different source of care. We note further that allowing this expedited process in cases where there is a change of drug plan obviates the need for limitations to the SEP for beneficiaries in the program.

We strongly support CMS's proposal to disallow such expedited procedures when the gaining plan does not include the same prescriber and pharmacy previously chosen by the beneficiary. Beneficiaries should always have opportunities to choose their best and most convenient source of care.

CMS also proposes not to allow for expedited notification and implementation under other circumstances, including when there are significant concerns regarding the health or safety of a

beneficiary or significant drug diversion activities. We agree with this position. However, an exception for "health or safety" is too broad within a drug management program that is premised on limiting drug availability to preserve the health and safety of beneficiaries. In addition, because the entire program curtails beneficiary rights, notice is a vital component. Any expedited process must be very strictly limited to circumstances where the beneficiary already had notice from a prior plan sponsor.

II.A.1(c)(2)(viii) Provisions Specific to Limitation on Access to Coverage of Frequently Abused Drugs to Selected Pharmacies and Prescribers (p. 56354)

(1) Beneficiary Preferences (p. 56355)

CMS proposes that plan sponsors must accept beneficiary choices for prescribers or pharmacies so long as the beneficiary choices are in-network, when applicable. If the beneficiary chooses an out-of-network pharmacy or prescriber, the sponsor is not required to comply with the beneficiary's choice unless it is necessary to provide reasonable access. Justice in Aging supports the CMS proposal. However, when a beneficiary expresses a preference for an out-of-network provider or pharmacy, we encourage CMS to establish a threshold to determine reasonable provider and pharmacy access standards. For example, the agency could designate that no more than a 20% increase in travel distance for a provider or pharmacy from the preferred or current providers should be permitted. CMS should also ensure that beneficiaries have a mechanism to counter sponsor decisions about "reasonable access" when a pharmacy or provider designed for the lock-in is unacceptable to the beneficiary despite appearing to meet the designated threshold.

CMS also proposes that the second notice beneficiaries receive should, when possible, confirm the beneficiary's selection of prescribers and/or pharmacies. Sponsors must also accept beneficiary selections at any time and must provide written confirmation of actions within 14 days of receipt. We support these timelines and notifications.

Beneficiaries must also be able to obtain their prescriptions in circumstances such as prescriber unavailability or beneficiary travel. Contingency plans must also be in place in the event of natural disaster or if needed medications are out-of-stock at a designated pharmacy.

(2) Exception to Beneficiary Preferences (p. 56356)

CMS proposes that plans should only be able to deviate from beneficiary preference upon a strong showing of inappropriate action. We strongly support this proposal and agree with the 30-day notice requirement.

When sponsors are choosing prescribers or pharmacies for beneficiaries, there must be strict requirements that sponsors are neutral with regard to designation of pharmacies and providers. These programs should not depend on business relationships that plan sponsors may have with certain providers and/or pharmacies.

(3) Reasonable Access (p. 56356)

CMS proposes to interpret CARA as promoting beneficiary preference above plan evaluations or designations of "reasonable access." CMS also requires plans to ensure reasonable access in the case of emergencies, disasters, or multiple residences.

We strongly support the beneficiary's preferences prevailing over plan access standards. As stated above, we encourage CMS to establish a threshold to determine reasonable provider and pharmacy access standards. For example, the agency could designate that no more than a 20% increase in travel distance for a provider or pharmacy from the preferred or current providers should be permitted. CMS should also establish mechanisms to ensure that beneficiaries can communicate about circumstances

where a pharmacy or provider designed for the lock-in meets the designated threshold, yet for individual reasons may still present an unacceptable burden for the beneficiary with respect to time, distance, and/or travel.

In addition to emergencies, disasters, or multiple residences, beneficiaries must be able to obtain needed medications when traveling outside of the range of their locked-in pharmacy for other reasons. Access must also be guaranteed when the designated pharmacy may be out of stock or unexpectedly closed or when a prescriber is on vacation or is otherwise unavailable.

II.A.1(c)(2)(ix) Drug Management Program Appeals (p. 56357)

CMS proposes to integrate various forms of appeals arising from a beneficiary's at-risk determination into one appeals process. We support this integration, which should improve the beneficiary's ability to appeal any burdensome consequence of the determination with one process.

We strongly object to beneficiaries not having appeal rights during their designation as "potential" at-risk beneficiaries. CMS proposes to include in this designation a limitation on SEP rights and, as such, it would affect important rights flowing from the individual's dual eligible status.

CMS proposes to use the deeply flawed current Part D appeals process for appeals of at-risk status or other consequences of drug management, arguing that this appeals process is already familiar to beneficiaries. We strongly oppose continued use of the reconsideration level and the lack of any provision for auto-escalation. Congress could have easily utilized the existing Part D appeals process if it wished CMS to simply insert this at-risk status designation into that process. Instead, CARA contemplates a more streamlined process that is easier for beneficiaries to navigate and requires plans to make better decisions in the first instance, rather than relying on a second or third bite at the apple.

The current Part D appeals process is overly burdensome for beneficiaries, and the reconsideration level in particular creates an unnecessary hurdle. By forcing beneficiaries who are determined to be at-risk into this deeply flawed process, CMS would increase the risk of unnecessarily and inadvertently cutting off access to needed medications at particularly vulnerable moments in beneficiaries' lives.

Without significant changes to the problematic appeals process, we cannot support thrusting additional beneficiaries into this system. Automatic escalation of beneficiary appeals, on the other hand, would allow for independent review of plan designations and improved tracking and monitoring of the scope and impact of the lock-in program. It would also provide for more uniform decision making across different plan programs without increasing burden on beneficiaries.

II.A.1(c)(2)(x) Termination of a Beneficiary's Potential At-Risk or At-Risk Status (p. 56358)

CMS proposes that the duration of a beneficiary's at-risk status not exceed 12 months or a determination that the beneficiary is no longer at risk. We support this time limitation.

II.A.1(c)(2)(xi) Data Disclosure and Sharing of Information for Subsequent Sponsor Enrollments (p. 56359)

CMS proposes to codify current policy and expand the scope of current reporting from sponsors about all pending, implemented, and terminated limitations on access to coverage of frequently abused drugs associated with their plans' drug management programs. We support this codification and expansion and, once again, point to this policy as evidence that limiting the SEP rights for beneficiaries designated as potentially at-risk or determined to be at-risk is an unnecessary infringement on low-income beneficiaries' ability to tailor their Medicare coverage to best suit their circumstances. Beneficiary choice and self-direction are most needed for those beneficiaries whose incomes are so low that even minor changes can prove a significant burden or significant advantage.

II.A.2 Flexibility in the Medicare Advantage Uniformity Requirements (p. 56360)

CMS is proposing to allow Medicare Advantage plans to offer tailored supplemental benefits that would only be available to subsets of plan members who have specific diagnoses. The agency proposes to issue guidance to plans for the 2019 plan year, which would need to be available even before these regulations are finalized.

Justice in Aging has supported the value-based insurance design (VBID) demonstration which is currently testing this approach and urge CMS to continue the VBID demonstration and share its results. That demonstration is expanding and will be available in 23 test states in 2019. We are hopeful that the demonstration will produce approaches that can be applied both to Medicare Advantage and fee-for-service Medicare. We also appreciate that the demonstration includes specific consumer protections and sets parameters for plans. Based on the results of the VBID demonstration, we would support extension of approaches that have demonstrated effectiveness in improving beneficiary outcomes. We believe it is premature, however, for CMS to move now to extend this flexibility to all plans while the VBID demonstration is still in its early stages and when there has been limited opportunity for evaluation and learning. We also question how the proposed national opportunity for plans to offer tailored benefits would affect the progress and viability of the VBID demonstration and whether plans would continue to be interested in participating in VBID, all issues that CMS failed to address in the NPRM.

We urge CMS not to make this change until the VBID demonstration can be evaluated and analyzed, and then only to make changes which are consistent with the learning that emerges from that demonstration. If, however, CMS decides to move forward immediately, we urge the agency to consider a number of issues, many of which we have raised before in the context of the VBID demonstration.

As advocates for low-income beneficiaries, we are particularly focused on the challenge in creating incentives that will be effective with all similarly situated members of the targeted subgroups. Financial incentives, such as reductions or elimination of co-pays for specific services, would be ineffective for dual eligible and QMB plan members who are already protected from co-payment liability. In a similar vein, the incentive of additional supplemental benefits would be of little value for a dual eligible if those additional services were already available through the beneficiary's Medicaid benefit. Since significant numbers of dual eligibles are enrolled in Medicare Advantage plans that are not D-SNPs, we ask that CMS require that tailored supplemental benefits be designed to address the needs of and incentivize both dual eligible and non-dual members of the targeted groups.

Other important considerations include:

- Provider and beneficiary education about the supplemental benefit: To ensure that all beneficiaries who qualify for the supplemental benefit have access to it, education of both beneficiaries and their providers is critical. This has been borne out in the Medicare and Medicaid financial alignment demonstration in which CMS granted plans the option to offer supplemental home and community based services. In evaluations of the program, however, providers and beneficiaries reported that they were unaware that the plans offer these services

and the evaluation recommended that plans conduct more education and outreach to inform members and providers of the availability and scope of these additional services.[5]

Since plans know the treatment records of their members, we ask that CMS require participating plans to put in place robust and targeted outreach to members with qualifying conditions and their providers, with particular emphasis on reaching those with limited proficiency in English, those who are homeless, and other hard-to-reach groups and providers who serve them.

- Reporting, monitoring, and evaluation: We ask that CMS require plans to report data, including the number of individuals believed eligible for each supplemental benefit and the number using each benefit, stratified by sex, ethnicity, dual status and other relevant categories. We also ask for rigorous evaluation of the impact of the supplemental benefits on beneficiary outcomes as well as an evaluation of access to the benefit, looking especially at whether the benefit is used across the spectrum of plan members, including those from underserved communities. Both the reporting and the evaluations should be publicly available so that outside experts and researchers, as well as CMS, can evaluate and learn from the data.

  Again, the financial alignment demonstrations offer lessons learned. To date, there has been very little data reported publicly on supplemental benefits the plans are delivering, even when those supplemental benefits are not targeted to specific populations. Self-reports from beneficiaries have been mixed. Some beneficiaries report increased access to flexible benefits,[6] while others, as noted above, report not being aware that such benefits are available. Formal reporting requirements will ensure plan accountability in the delivery of benefits.

  The demonstrations have also exhibited the importance of tracking the impact of supplemental benefits on health outcomes and costs. For example, in the California financial alignment, the provision of supplemental benefits has helped beneficiaries transition from nursing facilities to lower-cost community settings. Tracking of benefits and outcomes will allow CMS to evaluate the efficacy of supplemental benefits.

- Appeals: Criteria for supplemental benefits should be spelled out in detail and publicly available. Plan members should have full appeal rights with respect to denial of or limitation of access to supplemental benefits. A formal appeals process ensures that supplemental benefits are provided uniformly and fairly, and that beneficiaries are afforded due process protections,

[5] University of California San Francisco and Berkeley, "Provision of Home- and Community-Based Services through Cal MediConnect Health Plans," (November 2017), available *at* www.thescanfoundation.org/sites/default/files/ucb_researchbrief_hcbs_final.pdf?utm_source=11%2F29%2F2017+TSF%3A+Integrating+HCBS%3B+CHCS+Brief%3B+Pacesetter+Prize+Webinar+&utm_campaign=11%2F29%2F17&utm_medium=email.

[6] RTI, "Beneficiary Experience: Early Findings from Focus Groups with Enrollees Participating in the Financial Alignment Initiative," ("Focus Groups")(March 2017), available at www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/FocusGroupIssueBrief508032017.pdf.

including notices that explain the basis for a denial of benefits, and access to a decision-maker independent of the plan.

- Limit to high performing plans: Since this proposal is new and a significant departure from current practice, we ask that CMS limit its introduction to high performing plans, those that have earned at least three-and-a-half stars. To protect beneficiaries, three star plans, with only average performance, should be excluded, at least in the first years.

- Marketing: The VBID demonstration places limits on marketing to targeted benefits except to beneficiaries who are already plan members. We ask that this significant beneficiary protection be included if CMS expands flexibility to the entire Medicare Advantage market.

- Proposed guidance: The NPRM states that CMS is considering issuing guidance clarifying the flexibility it would offer plans. We ask that CMS open its proposed guidance to public comment prior to issuance.

II.A.3 Segment Benefits Flexibility (p. 56361)

With no discussion of rationale, criteria or anticipated impact on beneficiaries, CMS is proposing to allow plans to vary benefits within segments of a local plan service area. The agency notes that it already allows segmentation of premiums and co-insurance in market segments where plans have submitted separate bids under 42 CFR 422.254.

In discussing this proposal, CMS has not provided any information on how many plans currently take advantage of the opportunity for market segmentation for premiums and co-insurance, how many beneficiaries are affected or how plans currently communicate market segmentation of premiums and co-insurance to beneficiaries, brokers, and counselors.[7] The proposal also does not discuss any review or analysis that the agency has undertaken to determine whether beneficiaries have experienced confusion or whether there has been any evidence that the practice has had discriminatory impact or led to cherry picking of beneficiaries.

This absence of data on the impact of current segmentation flexibilities raises many concerns for us about how the proposal to allow different benefit packages in segments of a plan's local service area would work and how it would affect beneficiaries. We are particularly concerned because differences in benefit packages are much more difficult to communicate and to understand than different premiums and co-insurance.

Without sufficient explanation in the proposal, our major question is simply how this all would work. What would be the criteria that CMS would use to judge proposed benefit segmentation? Would a plan be allowed to segment both premiums/co-insurance and benefits? Would different provider networks in different segments be allowed? How would the Plan Finder reflect benefit segmentation? Would plans have different member handbooks for each segment or rely on asterisks and footnotes? What happens

[7] As advocates, we had not been aware of any plans using the current flexibility to segment markets for premium and co-insurance levels, nor do we know of any publicly available source from which this information could be extracted.

if an individual moves from one segment area to another during the plan year? Does that trigger an SEP? How will CMS monitor potential discriminatory impacts, beneficiary confusion, comparative outcomes, etc.?

We worry about the potential for discrimination against high-need, high-cost individuals living in low-income communities and rural areas. Our concern is heightened by the fact that many of the same high-cost potential plan members in these areas also qualify as QMBs and, because of their protection from deductible and co-insurance, are less profitable to plan providers.

We expect significant beneficiary confusion. If they are expected to make rational market-based decisions about their health coverage, beneficiaries need information that is clear and capable of being presented simply in a way that allows them to easily compare their choices. We have little confidence that this proposal, at least in its current open-ended form, could meet that test.

If CMS intends to move forward with this proposal, we urge the agency, at the very least, to test this change on a small scale with a few high-performing plans and a limited number of affected beneficiaries. This proposed change is a significant one. Data issues, Plan Finder issues, broker training, call center training, prior authorization procedures and many more technical details need to be tested. The ability of beneficiaries and their providers to comprehend differences needs to be assessed. All this needs to be done before a decision to undertake a general rollout of a change like this one.

II.A.4 and 5 Maximum Out-of-Pocket Limit & Cost-Sharing Limits for Medicare Parts A & B Services (p. 56361)

Justice in Aging supports CMS's deliberate, step-by-step approach to considering changes to the voluntary Maximum Out-of-Pocket Limits (MOOPs) and cost-sharing limits for Medicare Parts A & B services. We appreciate that CMS made clear in this proposed rule that it will continue to use the 85th and 95th percentiles of projected beneficiary OOP spending to set lower MOOP limits immediately, and is proposing a limited change now to allow it to consider other factors or percentiles in the future. We urge CMS to replicate this deliberate approach in other areas of this rulemaking to ensure that its proposals are tested and that stakeholders have ample opportunity to provide feedback.

Additionally, before making any further changes to the current MOOP levels or adding service categories permitted to have higher cost-sharing, we urge CMS to carefully consider the likelihood of increased complexity for beneficiaries in evaluating their plan options. Such changes would make it more difficult to understand what services a given plan covers and the applicable cost-sharing, especially when layered on CMS's proposals to loosen uniformity requirements and eliminate meaningful difference requirements. As with other proposed changes in this rule, we strongly urge CMS not to make any changes to MOOPs or cost-sharing limits without first ensuring that beneficiaries have the tools, such as an improved Plan Finder, that allow them to fully evaluate and compare their choices.

We also appreciate that CMS is focusing on preventing discriminatory benefit designs in developing policy with respect to MOOP and cost-sharing limits for Medicare Advantage plans, and we encourage CMS to continue that focus. Determining nondiscriminatory cost-sharing limits and enforcing them are essential to ensuring that MA plans do not try to dissuade enrollment by or otherwise discriminate against Medicare beneficiaries who utilize more or costlier care. In evaluating whether cost-sharing is discriminatory and setting cost-sharing limits, we encourage CMS to use the most appropriate data, including Fee for Service and Medicare Advantage utilization encounter data. We recommend that CMS

consider also permitting use of Marketplace Qualified Health Plan review data to evaluate the possibility of discrimination, especially when Medicare FFS or Medicare Advantage data are not available or insufficient (e.g., where a Medicare National Coverage Determination (NCD) or local coverage determinations (LCD) result in coverage for a service that has been covered in the individual market, but where no Medicare data are available).

II.A.6 Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (p. 56363)

In its proposal to eliminate the meaningful difference standard entirely from both Medicare Advantage and Medicare Part D regulations, CMS acknowledges that research has shown that consumers, particularly those who are old and frail, already are challenged in making choices among plans, and that their confusion often leads to inertia.[8] These concerns, combined with the fact that in earlier years several plan sponsors were offering different products that had very few differences in actual benefit design, had motivated the agency's decision to impose a meaningful difference requirement in the first place.

CMS now "is concerned the meaningful difference requirement results in organizations potentially reducing the value of benefit offerings," but offers no objective support for this concern.[9] The agency is concerned about unintended consequences that stifle innovation.[10] It also expresses confidence that Plan Finder improvements and other consumer engagement tools and outreach will address any issues of beneficiary confusion that might arise.

Justice in Aging's primary concern is that the total lifting of the meaningful difference requirement will swing the pendulum too much away from beneficiary protection. If CMS thinks that particular elements of the current standard are hurting innovation, then we urge CMS to carefully test what happens if those particular elements are changed or adjusted. It is premature to totally eliminate the regulation without first testing, either by demonstration or by small changes, the impact of modification of the standard.

For these reasons, we oppose eliminating the meaningful difference requirement, and urge CMS not to go forward at this time. This change, particularly when added to the proposals in this rulemaking to change requirements for supplemental benefits, is new, very significant and likely to have unanticipated impacts.[11]

If, however, CMS goes forward with its proposal, we urge:

- That CMS not implement the proposed flexibilities until changes to the Plan Finder are in place that allow beneficiaries to compare plans with respect to access to particular providers and to particular benefits. Plan Finder improvements should precede, rather than catch up with, changes in plan flexibility. While we appreciate the changes in the Plan Finder that CMS has instituted, they are insufficient to fully assist beneficiaries with current choices and would be

[8] 82 Fed. Reg. at 56363, including references cited in footnotes 27 and 28.
[9] 82 Fed. Reg. at 56364.
[10] *Id.*
[11] We note in the recent RFI issued by the Center for Medicare and Medicaid Innovation, the agency expressed a preference for small-scale testing before scaling up. See https://innovation.cms.gov/Files/x/newdirection-rfi.pdf.

even more inadequate with the flexibility proposed in these regulations. Beneficiary advocates would be happy to work with CMS on Plan Finder improvements.

- That CMS provide support and seek additional funding for the SHIP program and other beneficiary counseling, so that individuals can get help choosing among increasingly diverse Medicare choices.
- That CMS expand and strengthen the Medicare ombuds program so that, having chosen their Medicare plan, beneficiaries can get help navigating their benefit. Currently, the Medicare ombuds, though helpful to national advocates on particularly difficult issues, is not set up to field a wide range of beneficiary and advocate calls.
- That CMS oversee, closely monitor, and evaluate Medicare Advantage plan operations and results to determine whether the additional flexibility given to plans does in fact help beneficiaries and lead to better health outcomes. Further, CMS must carefully monitor for discriminatory plan benefit packages. When more flexibility is available to plans, more monitoring—not less—is needed to protect beneficiaries from unintended consequences.

II.A.7 Coordination of Enrollment and Disenrollment through MA Organizations (Default Enrollment into D-SNPs) (p. 56365)

The current CMS proposal would allow default enrollment into D-SNPs, with state approval, primarily for two populations: 1) adults enrolled in MAGI Medicaid who turn 65, continue to be eligible for Medicaid, and are eligible for Medicare Part A and Part B; and 2) individuals of any age who were enrolled in Medicaid on the basis of disability and, after their 24 month waiting period, become eligible for Medicare.

We appreciate that the current proposal significantly narrows default enrollment from the broader parameters originally permitted for seamless enrollment. We thank CMS for listening to the concerns of beneficiary advocates about the earlier design and for the agency's thoughtful analysis of the issues that seamless enrollment presents. 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 90-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.[12] 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.
- The D-SNP provider network should be substantially similar to the network in the Medicaid plan.

[12] 82 Fed. Reg. at 56370.

- 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 in 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 clarification as to whether and when individuals who had ESRD while in a Medicaid managed care plan will be subject to default enrollment.[13]

We also ask for a notice process involving at least two notices. We discuss this process more fully in the section of these comments on passive enrollment and ask that it be applied to default enrollment as well. Further, as with all the major enrollment and benefit design changes proposed in this rulemaking, we are concerned that many proposed details of the opt-in process and the associated beneficiary protections and disclosures are not yet available. The unrealistically tight timeframe for developing details on the many changes proposed in this rulemaking severely limits the opportunity for a meaningful stakeholder process.

CMS also stated that it may rescind or suspend approval for default enrollment at any time if it is determined that a plan is not in compliance and asked for comment on broader authority to set a time limit on the approval. We believe that a two year time limit is appropriate. A time limit would give CMS and the states an opportunity to review the success of default enrollment and determine the impact on beneficiary services and health outcomes. Further, without a set limit, it is possible that a plan's compliance with set standards would be the sole criterion for continuing approval. With a two year limit, CMS and the states could periodically review not just compliance with a set of rules but also, and more importantly, the impact on beneficiaries and their health outcomes. Periodic review is especially important since CMS and the states have had limited experience with default SNP enrollment and it is likely that unexpected issues will arise.

The NPRM also asked for comment on the agency's decision to allow opt-in enrollment into Medicare Advantage plans for individuals transitioning from commercial products of the same sponsor. We agree with CMS's decision to limit this enrollment to an opt-in basis. As CMS has noted, default seamless enrollment from commercial plans presents technical challenges around identification of affected beneficiaries and proper notice. Further, the mere fact that a Medicare Advantage plan and a commercial plan have the same sponsor does not necessarily mean that there is much overlap in provider networks or program design. More importantly, default seamless conversion from commercial plans into Medicare Advantage plans could apply to so many new beneficiaries that it would threaten the basic clear statutory intent of Section 1851(a)[14] that fee-for-service Medicare be the default enrollment for individuals who do not choose. A broad exception for seamless conversion could easily swallow up this core statutory mandate.

[13] 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 cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/CY_2018_MA_Enrollment_and_Disenrollment_Guidance_6-15-17.pdf.

[14] 42 U.S.C. 1395w-21(a).

CMS also invites comments on alternative proposals, specifically codifying the existing parameters for seamless conversion default enrollment, so that all MA organizations could use the default enrollment process. We oppose these alternatives, as they lack the beneficiary protections enumerated in the current CMS proposal and described above. Further, we also oppose creating distinctions among Medicare beneficiaries by age and allowing the use of default enrollment only for the aged population.

II.A.8 Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dual 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.[15] 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 understand that the goal of this proposal is to provide continuity to dual eligibles affected by contract changes, and we appreciate the narrowness of the proposal. 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.[16]

Justice in Aging has 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 through 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 original 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 support 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 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

[15] Proposed 42 C.F.R. 422.60(g)(iii).
[16] 82 Fed. Reg. at 56434.

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 learned from the dual eligible financial alignment demonstrations, it is important that these policies be easy for beneficiaries and providers to navigate.[17]

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:[18]

- 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.
- 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.[19]

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.[20]

---

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

[18] *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.

[19] See 45 C.F.R. 92.8(d).

[20] 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.

II.A.9 Part D Tiering Exceptions (p. 5637)

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. Very little information exists for beneficiaries, and what information beneficiaries have is difficult to understand and apply to individual situations. Education should include beneficiary notices, in particular at the pharmacy counter. Additionally, CMS should provide clearer information through 1-800-MEDICARE about the tiering exceptions process and how beneficiaries may engage in it if necessary. In addition to education from CMS, plans and pharmacies should have responsibility for educating beneficiaries on the tiering exceptions process.

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. It may be possible, for example, to have a box on exception request forms to ask also for a tiering exception if available.

II.A.10 Establishing Limitations for the Part D SEP for Dually Eligible Beneficiaries (p. 56374)

CMS proposes to dramatically limit the Special Enrollment Period (SEP) for dual eligibles, which is statutory,[21] as well as the SEP for all LIS beneficiaries. CMS would eliminate the continuous SEP for both duals and LIS beneficiaries and, instead, create a more restricted set of SEPs. Justice in Aging strongly objects to this proposal and believes 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.

While we recognize the importance of care coordination, as well as concerns about abusive marketing and plan burden, this proposal is not the way to address these issues. 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.

[21] 42 U.S.C. 1395w-101(b)(3)(D).

- 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 CARA.
- 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.[22]
- We question why limiting beneficiary options is the preferred response to abusive marketing to dual eligibles. Refining marketing rules and providing continuing oversight seem to us to be more effective responses to abusive behavior.

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.[23]

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 for the category of beneficiaries who are least able manage that 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 that the regulations provide.

[22]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.

[23]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.

If, however, CMS moves forward with the proposal, we request that CMS, at the very least, 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.[24] 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 election has been used."[25] 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.

II.A.11 Medicare Advantage and Part D Prescription Drug Program Quality Rating System (p. 56375)

b. Background (p. 56376)

CMS solicits feedback on how well the existing star measures create meaningful quality improvement incentives and differentiate plans based on quality. In particular, CMS seeks information about additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans. We continue to support CMS' efforts to provide better information for beneficiaries on the star rating system. As CMS notes, the purposes of the quality rating system are to provide comparative information to Medicare beneficiaries, to identify and apply the payment consequences for Medicare Advantage plans, and to evaluate and oversee overall and specific performance by plans. These purposes are a strong reason to ensure that audit findings, including sanctions for significant deficiencies, are meaningfully incorporated in the star ratings.

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.

f. Contract Consolidations (p. 56380)

CMS worries that the current practice of assigning the surviving contract the star rating that the contract would have earned without regard to whether a consolidation took place results in masking low quality plans under higher-rated surviving contracts. This does not provide beneficiaries with accurate and reliable information for enrollment decisions, and it does not truly reward higher quality contracts.

To combat this, CMS proposes instead to assign and display star ratings based on the enrollment-weighted mean of the measure scores of both the surviving and consumed contracts so that the ratings reflect the performance of all contracts (surviving and consumed) involved in the consolidation. Under

[24] 82 Fed. Reg. at 56374.

[25] cms.gov/Medicare/Eligibility-and-Enrollment/MedicarePresDrugEligEnrol/Downloads/CY_2018_PDP_Enrollment_and_Disenrollment_Guidance_6-15-17.pdf.

this proposal, the first and second year's ratings would be so calculated, while the third year would be based solely on the performance of the entire contract.

We support this 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. As CMS notes, the current practice can allow very poor plans to hide under the ratings umbrella of a highly-rated plan, and this skews the entire market's ratings.

h. Adding, Updating, and Removing Measures (p. 56382)

CMS proposes to codify key aspects of the current star ratings methodology and delineates the principles for adding, updating, and removing measures, including the use of formal rulemaking processes under certain circumstances while retaining the use of Call Letters as a valid avenue for tweaking measures when necessary. We understand that rolling the star ratings process into regulation, rather than the Call Letter process, substantially extends the time from initial proposal of measures to inclusions of measures in the program, though it will add administrative rigor to the star ratings program. However, increasing the time from measure consideration to use could limit the ability of CMS to respond to the changing landscape of quality measures. While CMS rightly suggests that the universe of quality measures has matured somewhat, we believe that there is still significant upheaval in the design of such measures that may make the formal rulemaking process less nimble than necessary.

q. Measure Weights (p. 56401)

CMS appears to propose to increase the weight of patient experience/complaints and access measures to 3 or nearly 3. We support increasing the weight of these measures as they reflect how patients interact with plans. By increasing the weights of these measures, CMS ensures that beneficiaries are seeing star ratings that reflect the things they are likely to find important about their plan selections.

t. Categorical Adjustment Index (p. 56404)

CMS proposes to stratify quality measure reporting by demographic data such as dual eligibility or low income and disability status. We support such stratification as an important tool for uncovering disparities and quality gaps as well as identifying intervention points and strategies.

u. High and Low Performing Icons (p. 56406)

CMS proposes to continue a policy that does not allow beneficiaries to enroll in low-performing plans via the Medicare Plan Finder tool. Beneficiaries who still want to enroll in a low-performing plan or who may need to in order to get the benefits and services they require (for example, in geographical areas with limited plans) will be warned, via explanatory messaging of the plan's poorly rated performance, and directed to contact the plan directly to enroll. The high number of plans available to people with Medicare in most regions can lead to beneficiary confusion. Because of this, we support limitations on plans' ability to enroll beneficiaries online where there is a significant chance they have not fully understood the implications of enrolling in a low-quality plan.

II.A.12(a) Any Willing Pharmacy Standards, Clarification to "Any Willing Provider" Requirements (p. 56408)

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.

II.A.12(b) Definition of "Mail-Order Pharmacy" and "Retail Pharmacy" (p. 56408)

We appreciate and support the proposed clarification of retail and mail order pharmacy distinctions. Retail pharmacies that provide home delivery, either occasionally or routinely, offer a valuable service. Nothing in the Part D regulatory scheme should discourage the practice or make it more difficult for locally-based pharmacies to participate in the program. We support CMS in seeking to remove impediments to robust retail networks, a need that is particularly important for beneficiaries in underserved areas, including rural areas and small towns.

II.A.14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (p. 56413)

CMS proposes to allow plans greater flexibility for generic substitutions. Specifically, plans could immediately, at any time of year and without 60-day notification, remove a branded product or change cost sharing to a higher amount when opting to cover a therapeutically equivalent, newly approved generic drug.

We oppose this change. An unanticipated change in pills can cause significant confusion for beneficiaries. Older adults often take many pills each day. They and their caregivers are warned to be careful not to mix their pills, not to take the wrong one, never to take someone else's pills, etc. Getting a drug in a different size or color without notice could easily cause concern and affect adherence. A sudden change in cost sharing could have similar effects. A generalized advance notice with retrospective specific notice, as suggested by CMS, would do little to address these concerns. If CMS chooses to proceeds with this change, to comply with the statutory requirement for notice, we urge CMS to continue to require individual notice, even if that notice were shortened to 30 days instead of the current 60 days.

II.A.15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing (p. 56416)

We support CMS' proposed revision of the definition of generics to include biosimilars for purposes of cost sharing. Encouraging the use of biosimilars among LIS beneficiaries and non-LIS enrollees, where medically appropriate, could increase price competition among biological products, with positive impact on both beneficiaries and program costs.

II.A.16 Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences (p. 56417)

We are concerned about the removal of the meaningful difference requirement in Part D. As with our objections to this proposal for Part C plans, our concerns are that beneficiaries, already confused by the many differences in plan design, will have even less opportunity to make an informed choice.

CMS should instead address any current concerns about the meaningful difference standard by introducing modifications to the standard. The agency could also consider a waiver of the meaningful difference requirement only in cases where plan sponsors can show that there are significant differences in value between their enhanced offerings even when the differences in expected out-of-pocket costs do not exceed the threshold. Even in those cases, we strongly encourage CMS to remain vigilant in ensuring that differences in plan characteristics and benefit designs reflect significant differences in value, are not discriminatory, and that beneficiaries can evaluate and compare their options in an informed manner. Ensuring that Medicare Plan Finder tool allows beneficiaries to understand the differences among plan options will be especially important.

We support CMS' proposal to continue use of the meaningful difference requirement between basic and enhanced plans. Eliminating this requirement could result in sponsor behaviors that could adversely

affect the program, such as offering enhanced plan options to engage in risk segmentation, a concern that prompted the meaningful difference standard when it was first introduced.[26]

II.A.17 Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale (p. 96419)

We appreciate that CMS is seeking to develop a more transparent approach to the treatment of rebates. As the agency has noted, the current system is not resulting in lower costs for beneficiaries at the point of sale, and may shift government costs to the catastrophic phase of the benefit.[27] As CMS is seeking improvements, we urge the agency to make careful evidence-based determinations to ensure that the incentives promote the greatest possible increase in beneficiary access to affordable drugs. We also urge CMS to develop a system that allows beneficiaries to make fully informed choices among their drug coverage options.

II.B.4 Revisions to Timing and Method of Disclosure Requirements (p. 56431).

Justice in Aging supports the separation of the mailing of the Annual Notice of Change (ANOC) and the Evidence of Coverage (EOC). This simple change will allow beneficiaries to examine the documents separately rather than be overwhelmed by them in the same mailing, and in particular, encourage beneficiaries to focus on the information contained in the ANOC during the process of plan selection. It is crucial that the ANOC continue to be delivered at least 15 days before open enrollment, to allow beneficiaries sufficient time to understand changes to their health insurance, so they can make a change if they desire.

In addition, citing increased use of the internet by Medicare beneficiaries, CMS proposes to allow plans to provide the Evidence of Coverage (EOC) and the Summary of Benefits electronically unless a beneficiary affirmatively requests a hard copy. We oppose this change and instead ask that CMS allow plans to offer alternative delivery by electronic means that beneficiaries must opt in to.

While we recognize that internet use is growing and support encouraging plans to *offer* electronic delivery, we do not believe that the statistics CMS cites support the proposal to make electronic delivery the default. CMS states that half of seniors have access to broadband at home, which means half do not. While using the internet on a phone or mobile device is becoming more common, home broadband access is actually declining, which is considered a major disadvantage for accessing both government services and health information.[28] Further and not surprisingly, CMS reports that internet usage is skewed to younger seniors. Thus older seniors, who statistically are likely to be sicker and have more chronic conditions and thus a greater need to understand the details of their coverage, are those who are least likely to have access to electronic materials.

---

[26]In implementing the meaningful difference rule, CMS noted that "it was urgent that we adopt the proposed policy as soon as possible so that we could bring an end to this bidding practice" that allowed some plan sponsors to offer "low value enhanced plans" that had premiums below the sponsors' basic plans due to favorable risk selection (Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule published on May 23, 2014.)

[27]Centers for Medicare and Medicaid Services. Medicare Part D-direct and indirect remuneration. Available at cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html

[28]Pew Research Center, Home Broadband 2015 (Dec. 21, 2015), available at www.pewinternet.org/2015/12/21/home-broadband-2015/. Home broadband access fell 3 percent between 2013 and 2014 and by even more among rural residents (5%), those with incomes less than $20,000 (5%), and African Americans (8%). Cost was the most commonly cited reason for not subscribing to broadband at home.

We have additional concerns that internet access, and particularly broadband access at home, remains less common in rural areas and among people with limited income and resources; both are demographics with relatively higher concentrations of seniors. In 2016, adults over age 65 made up 17.5 percent of the population in rural areas, compared with 14 percent of the total U.S. population.[29] At the same time, half of Medicare beneficiaries had less than $26,200 in income. According to Pew Research Center, only 27 percent of seniors with incomes less than $30,000 have broadband access at home and only 46 percent use the internet at all.[30] Furthermore, only 55 percent of rural residents had broadband at home in 2015.[31] Thus, we strongly believe that the internet usage trends do *not* support making electronic delivery the default for Medicare beneficiaries.

Furthermore, in most commercial settings, an opt-in approach to electronic communications is the norm. In the insurance context, more and more states allow electronic policy delivery but all that do require obtaining the consumer to affirmatively consent or opt-in.[32] Medicare beneficiaries who are more internet-savvy are used to opting into electronic access and it is reasonable to believe that they will do so in significant numbers. Therefore, we ask that CMS restrict plans to an opt-in process for expanding electronic delivery and disclosure.

In addition to the substantial lack of internet access among seniors, especially those with low-incomes and living in rural areas, we note that the hard copy disclosure requirements are codified as *beneficiary protections.* Ensuring beneficiaries have complete information in a format they can readily access is a key beneficiary protection and should not be compromised to save Medicare Advantage organizations money or effort. Therefore, we strongly believe that the cost-savings to Medicare Advantage plans, cited by CMS,[33] should not be a sufficient reason for changing this policy.

If, however, CMS moves forward with this proposal, we ask that the electronic delivery default be limited to the large Evidence of Coverage document and not include the Summary of Benefits, which most Medicare beneficiaries are likely to reference regularly. Furthermore, any beneficiary's request for a hard copy, for non-standard format, or for a translated document should be treated as a continuing request, to be honored for all subsequent documents unless and until the beneficiary changes preferences. Beneficiaries should not have to repeatedly ask for documents in their preferred format.

---

[29] PERCENT OF THE TOTAL POPULATION WHO ARE 65 YEARS AND OVER - United States -- Urban/Rural and Inside/Outside Metropolitan and Micropolitan Area, available at https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk.

[30] Pew Research Center, Technology Use Among Seniors (May 17, 2017), available at www.pewinternet.org/2017/05/17/technology-use-among-seniors/.

[31] Pew Research Center, Home Broadband 2015 (Dec. 21, 2015), available at www.pewinternet.org/2015/12/21/home-broadband-2015/

[32] *See* Heidi A. Zibel, Recent Law and Legislation for the Electronic Delivery of Insurance Documents, INSIGHTS (April 7, 2014), www.wolterskluwerfs.com/article/recent-legislation-for-the-electronic-delivery-of-insurance-documents.aspx

[33] 82 Fed. Reg. at 56339-40. We also note that plans will still experience substantial savings through an opt-in system, although CMS did not attempt to quantify those savings.

II.B.5 Revisions to Parts 422 and 423, Subpart V to Include Communications and Communications Materials (p. 56433)

CMS is proposing to establish two categories of materials, a narrower category identified as marketing materials and an umbrella category of communications materials, which encompasses marketing materials as well as all other communications from plans to beneficiaries. Agency review would only be required for documents that fall into the marketing basket. Justice in Aging believes that the general approach makes sense and will offer efficiencies. We have concerns, however, about the Evidence of Coverage, which CMS proposes to exclude from the marketing category, and the Summary of Benefits, about which CMS is silent but which, because it is an objective presentation of plan benefits, appears to be excluded as well. We urge CMS to treat both documents as marketing materials because their content can be critical to an enrollment decision, regardless of their tone or writing style. The Evidence of Coverage is sent to all members at the start of the AEP, a fact that reflects its importance in plan choice. It is not simply a post-enrollment reference.

We also note that CMS review of key documents is even more important if CMS moves forward with giving plans more flexibility on plan design and in the types of benefits that can be offered. Beneficiaries facing increasingly diverse choices need confidence that CMS has ensured that plan details are presented clearly and accurately.

In this section of the NPRM, CMS also is proposing to reframe the regulations covering translation of materials into non-English languages. We appreciate that, as proposed, translation regulations would encompass all communications, not just communication deemed to be marketing material, a change that would allow CMS to designate additional documents as subject to the translation requirements. We strongly urge CMS to undertake a program to expand the number of documents subject to the translation requirement, prioritizing those that most affect beneficiary rights and their access to services, e.g., disenrollment notices, notices denying services, lock-in notices, etc. An expansion of translated documents is long overdue. It would be consistent with the agency's obligations under Title VI of the Civil Rights Act of 1964 and Section 1557 of the Affordable Care Act and HHS implementing regulations and with the commitment of CMS to address disparities in health care. We note that many state Medicaid programs are far ahead of CMS in establishing comprehensive translation requirements for Medicaid managed care plans and that those requirements have not been unduly burdensome for plans. We urge the agency to consult with states that have broader translation requirements and work with other stakeholders on the project.

Further, we ask CMS to seriously consider additional rulemaking to modify the current translation thresholds, which are set at five percent of the population in the service area, by adding a numerical threshold. The current regulation leads to stunning anomalies. For example, a Medicare Advantage plan serving San Francisco County must translate documents into Chinese but a PDP serving the entire state of California, with a much larger Chinese LEP population, does not. Including numerical as well as percentage thresholds would lead to more rational results, particularly for PDPs that serve large populous states.

II.B.6 Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (p. 56437)

We recognize that collecting information sufficient to adjudicate a decision within 7 days can be a challenge in some cases; this is a shorter time period than that allowed in Part C. However, given our

concerns about the effect of this change on beneficiaries and the often significant hardship that beneficiaries face when paying out of pocket for needed drugs, we encourage CMS to keep the existing deadline for plan sponsors and the IRE.

In cases that are appealed to the IRE, existing deadlines provide enrollees with a decision within a total of 17 days from initial appeal. The proposed policy would add 14 days for a total of 31 days. Medicare beneficiaries on limited budgets would face increased financial burden under this proposal. Beneficiaries who wait up to a month to then learn that their case has been decided against them would have to either pay for the drug out of pocket again or get a prescription for an alternative drug within a short time period. These options jeopardize enrollees' access to needed drugs, either initially prescribed or alternative, in a timely manner.

II.B.7 Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE (p. 56438)

CMS proposes to eliminate the requirement that Medicare Advantage plans notify an enrollee when a reconsideration decision is deemed adverse or partially adverse to the enrollee and has been referred to the 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 the notices are duplicative but urge that CMS, instead of eliminating the plan letter, eliminate or delay the IRE letter. Beneficiaries receive a deluge of mail related to Medicare and they are much more likely to open a notice from their plan than from the IRE. Eliminating the plan notice could lead to beneficiary confusion about the status of their appeal.

II.B.11 Part C /Medicare Advantage Cost Plan and PACE Preclusion list (56448)

CMS is proposing to entirely abandon its requirement that participating providers in Medicare Advantage plans must be enrolled Medicare providers. Instead, plans could include in their networks non-participating providers as long as they are not on a preclusion list that CMS intends to establish. Though asserting that Medicare enrollment is the best way to ensure provider compliance with Medicare rules and standards, the agency is concerned that roughly 120,000 Medicare Advantage providers are not enrolled, noting "the burden involved in enrolling in Medicare while having to also undergo credentialing by their respective health plans" and expressing concern on possible effects on access to providers.

We have serious concerns about this CMS proposal. First, we agree with the reasoning that CMS laid for its earlier decision to add the requirement of enrollment in Medicare. CMS' reasons included ensuring that Medicare enrollees receive items or services from providers and suppliers that are fully compliant with the requirements for Medicare enrollment; assisting in efforts to prevent fraud, waste, and abuse; protecting Medicare enrollees by allowing CMS to carefully screen all providers and suppliers to confirm that they were qualified to furnish Medicare items and services; permitting a closer review of Medicare Advantage providers and suppliers; and allowing access to information and data not available to Medicare Advantage organizations.

In addition to the arguments favoring Medicare enrollment articulated by CMS, we ask CMS to consider the effect of the proposal on protection of Qualified Medicare Beneficiaries (QMBs) from improper

billing by in-network providers. It is the provider's enrollment in Medicare that gives CMS a direct path to enforcement against a provider that improperly bills a QMB. While we recognize that, by regulation, CMS requires plans to include billing protections in a provider contract, that provision simply does not afford the beneficiary the same level of protection that is afforded by CMS's ability to enforce the Medicare provider's contract with the agency.

Further, not requiring Medicare Advantage providers to be enrolled in Medicare can create problems for beneficiaries who disenroll from a Medicare Advantage plan and elect traditional fee for service Medicare. They may have a long-established relationship with an in-network provider but, because the provider is not enrolled in Medicare, cannot continue the relationship in traditional Medicare.

We urge CMS to reconsider its proposal and, if the enrollment requirement creates issues for some providers, address those issues more narrowly without completely jettisoning the Medicare enrollment requirement. We would first suggest additional inquiry into the facts behind the 120,000 providers who are not enrolled. For example, is non-enrollment concentrated in particular provider types or specialties, particular geographic regions, particular plan sponsors, etc.? If so, CMS could consider extending the 2019 deadline and undertaking more targeted outreach.

We also urge CMS to examine whether the enrollment requirement really has any substantial effect of plan ability to develop adequate provider networks. As CMS has noted, 930,000 plan providers are enrolled in Medicare. Our experience is that plans are narrowing their networks as part of delivery strategies and not because there are not enough providers available. In fact, the trend toward narrower networks increases the importance of having participating providers in those networks subject to Medicare credentialing.

Nevertheless, we can envision circumstances where highly specialized providers are needed and few within a specialty choose to enroll in Medicare. There may be other unique circumstances as well that would merit an exception to the general rule of Medicare enrollment. CMS could develop an authorization process that allows for those special circumstances and permits plans to bring providers into their networks so that beneficiaries have adequate access. This narrower approach would be preferable to the current proposal.

II.B.13 Reducing Provider Burden (p. 56455)

As CMS considers the comments regarding reducing provider burden, we urge the agency consider how plans can develop mechanisms that facilitate provider participation in care coordination, including production of medical records, without being overly burdensome. One of the asserted benefits of Medicare Advantage enrollment is the opportunity to receive more coordinated care. We have seen in the Medicare-Medicaid financial alignment demonstration that plans have faced some challenges in getting physician participation in care coordination meetings, full sharing of care information, and other coordination activities. Plans must ensure that the providers in their network share a commitment to the process of care coordination, and beneficiaries have a right to expect that commitment when they join a Medicare Advantage plan.

II.C.1(b) Proposed Regulatory Changes to the Calculation of the Medical Loss Ratio (p. 56456)

We are concerned by CMS's proposal to change how required fraud prevention activities are accounted for in Medicare Advantage plan Medical Loss Ratio (MLR) calculations. We agree that fraud prevention is

critical to the effectiveness of the Medicare program and to the safety and wellbeing of beneficiaries. However, we do not believe that CMS has justified the proposed changes to allow Medicare Advantage and Part D plans to include all fraud reduction activities as quality improvement activities (QIA). We urge CMS to analyze the potential impact of this policy before changing the regulations. Absent evidence that plans are *not* engaging in fraud prevention activities because of the costs that cannot be discounted in the MLR, we do not believe that this policy change is justified.

If CMS does move forward with changing accounting for fraud reduction activities in the MLR formula, we recommend ensuring that the MLR data be reported in such a way that the trends in plan spending on fraud reduction activities can be assessed.

We support the proposed change to clarify that Medication Therapy Management (MTM) programs offered by Part D and MA-PD plans are QIA for purposes of MLR calculation so long as they are compliant with § 423.153(d). We agree with CMS's intention to encourage plans to strengthen their MTMs to achieve better health outcomes.

II.C.1(c) Proposed Regulatory Changes to Medicare MLR Reporting Requirements (p. 56459)

We oppose CMS' proposal to reduce the Medicare MLR Reporting Requirements absent testing and analysis showing that the data and information to be omitted are unnecessary. As CMS notes, the MLR requirements are an important tool for incentivizing plans to reduce administrative costs and ensure they are spending their revenues on quality care for consumers and maximizing value. We are relieved to know that CMS is not proposing to weaken its authority to audit plans and enforce MLR compliance or relieving plans of the obligation to retain documentation. However, we are concerned that the very limited data CMS proposes requiring plans to submit will not provide sufficient information for CMS to detect MLR calculation errors or fraud. For example, seeing each plan's incurred claims and expenditures on quality improving activities allows CMS to detect outliers or unusual changes in spending patterns that may merit investigation. On the other hand, if plans are not required to report the components of their MLR calculation, it may encourage fraud in reporting that they met the 85 percent MLR threshold.

Furthermore, CMS seems to imply that requiring health insurance issuers to complete substantially different forms for Medicare MLR versus commercial MLR purposes is burdensome. However, we note that the MLR reporting requirements for commercial plans under the Affordable Care Act include much more detail such as earned premiums, claims data, and expenditures on quality improvement activities.[34] Thus, issuers are used to reporting these specific data and eliminating them from the Medicare MLR report would not align the reporting requirements across programs.

For these reasons, we do not believe that the limited efficiencies[35] MA and Part D plans gain from reducing reporting outweighs the risks of not being able to closely monitor MLR compliance.

[34] *See* 45 C.F.R. § 158.110 et seq.

[35] CMS estimates of savings for plans are minimal. The agency estimates the proposed change would save plans 11 hours and $1,542 per contract. 82 Fed. Reg. at 56473.

Conclusion

The extensive changes proposed in this rulemaking would have significant impacts on the lives of the millions of low-income older adults and people with disabilities who rely on Medicare. We urge CMS to ensure any changes that are undertaken to promote plan flexibility and efficiency also result in increased simplicity and improved outcomes for beneficiaries.

Thank you for considering our comments. If any questions arise concerning this submission, please contact me at jgoldberg@justiceinaging.org.

Sincerely,

Jennifer Goldberg
Directing Attorney