

January 16, 2018

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Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8016

Submitted electronically to www.regulations.gov

Re: CMS-4182-P

To Whom It May Concern:

The Medicare Rights Center (Medicare Rights) appreciates the opportunity to comment on the proposed changes to the Medicare Advantage, Medicare Fee-for-Service, and the Medicare Prescription Drug Benefit programs (CMS-4182-P). Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Medicare Rights provides services and resources to nearly three million people with Medicare, family caregivers, and professionals each year.

The following comments are informed by our experience assisting beneficiaries, their family members, and health care professionals as they navigate selecting and accessing care through a Medicare Advantage or Part D plan. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Casey Schwarz, Senior Counsel, Education & Federal Policy at CSchwarz@medicarerights.org or 212-204-6271.

General Comments

This Notice of Proposed Rulemaking (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. The Centers for Medicare & Medicaid Services (CMS) asserts that the changes will promote innovation and improve efficiency.

Medicare Rights has supported and continues 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, advance the goals of living safely in the community, and offer opportunities for better health outcomes. We have seen, however, that changes often give rise to unexpected results and unanticipated consequences. Strong beneficiary protections and responsive assistance mechanisms need to be in place to address individual and systemic issues that may 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 entirety, do not. To summarize our major concerns:

Scope and Timing. The scope of these proposals is very broad. They include changes to the Medicare program that would allow plans to offer supplemental benefits for only specific groups of beneficiaries, offer segmented benefits, and to give plans more leeway in designing Part C and D benefit packages. Most of these changes are expected to be available to plans for the 2019 plan year, though details generally have not yet been offered for comment or finalized.

Implementing so many changes so quickly in 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. 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.

Beneficiary Enrollment Choices. Current proposals to add flexibility for plans will add complexity 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. As CMS has noted, studies show that many beneficiaries are already overwhelmed and report that they feel unable to make a choice.

In proposing these changes, CMS has expressed confidence that improvements in the Plan Finder, the only tool for plan comparison, will help beneficiaries to 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. However, 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 drug coverage for plans and does not even 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 that the many proposals in this rule that offer plans more flexibility, and increase complication for beneficiaries, not be enacted until CMS gives beneficiaries adequate tools to evaluate and compare their choices.

At the same time that CMS is proposing significantly more flexibility for plans, it also is proposing to eliminate the continuous Special Enrollment Period (SEP) for dual eligibles and beneficiaries who qualify for the Low Income Subsidy (LIS), and replace it with a confusing set of limited SEPs. These restricted SEPs will be complicated to communicate to beneficiaries, and will lead to confusion about when and whether a beneficiary can change plans. Older adults and people with disabilities who use 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 can provide. Furthermore, they need enrollment procedures that they can easily understand.

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 plan performance. Oversight of plans 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 changes are actually resulting in improvements for beneficiaries.

II. Provisions of the Proposed Regulations

A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability

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

(2) Proposed Requirements for Part D Drug Management Programs (§§ 423.100 and 423.153)

(A) Definition of “Potential At-Risk Beneficiary” and “At-Risk Beneficiary” (§ 423.100)

CMS proposes to define two important categories of beneficiaries: “At-Risk Beneficiaries” and “Potential At-Risk Beneficiaries.” “Potential At-Risk Beneficiaries” are those who have been identified using the clinical guidelines by either the current sponsor or a previous sponsor. Medicare Rights is concerned by the implementation of any restrictions on those identified as potentially at-risk. Even though those identified as potentially at-risk have not been formally determined to be at-risk for misuse or abuse of frequently abused drugs, they will be, under the proposed rules, subject to limitations on their SEP rights and have no formal appeal rights at this stage. We discuss our objection to the SEP limitation more broadly below, but even should such limitations be included for individuals determined to be at-risk, those who have merely been identified as potentially at-risk must not have their access to consumer protections curtailed.

(B) Definitions (§ 423.100)

Frequently Abused Drug: CMS proposes 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. Medicare Rights strongly supports CMS’s proposal to limit the category of “frequently abused drugs” to opioids for the purposes of Part D drug management programs. 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, expansion of the Part D drug management program could be revisited. 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.

CMS seeks feedback on allowing sponsors to continue to implement drug management on non-opioid medications. We oppose allowing such expansion. In order to best protect beneficiary access to needed medication, a conservative and uniform approach should be implemented across all plans. This is especially important because a plan’s implementation of such restrictions may not be readily apparent or transparent to potential enrollees, and informed beneficiary choice is the bedrock of Medicare.

CMS proposes to prohibit plans from voluntarily reviewing more 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. Voluntary plan standards increase confusion and fragmentation across the Medicare landscape.

Medicare Rights urges CMS to ensure that plans do not have the latitude in developing or implementing systems for identifying potentially high-risk patients to either inadvertently or intentionally over-select for low-income beneficiaries, historically disadvantaged minorities, women, people with disabilities, or people with certain diagnoses. CMS should regularly monitor plan programs to ensure that such over-selection does not occur.

Exempted Beneficiary: CMS proposes that the new CARA implementation rules exempt recipients of hospice care, residents of certain long-term care facilities, and individuals with a cancer diagnosis. We encourage CMS to also exempt individuals receiving palliative and end-of-life care. CMS explains that they would expect the plan not to seek to implement a limit on such beneficiary's access to coverage of opioids under the current policy nor a drug management program. But this exposes such individuals to a potential risk of being included in the drug management program at the discretion of the plan, which may cut off access to vital pain-controlling medications when they are most needed.

(iv) Case Management/Clinical Contact/Prescriber Verification (§423.153(f)(2))

CMS proposes that 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 out a specific number of attempts in a specific time frame for post-notification contact. While Medicare Rights does 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 easily auto-forwarded to the Independent Review Entity (IRE) as required by the Act.

(vi) Requirements for Limiting Access to Coverage for Frequently Abused Drugs (§423.153(f)(4))

CMS proposes that sponsors must obtain prescriber agreement before implementing pharmacy lock-in. Medicare Rights supports this proposal, in that it will better ensure beneficiary access to needed medications. Providers are better positioned to understand and manage a beneficiary's use of frequently abused drugs and overriding a prescriber's professional judgment should require extreme circumstances.

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 would suggest a 30-day window for prescriber response is less likely to lead to avoidable disruption of needed medications.

(vii) Beneficiary Notices and Limitation of Special Enrollment Period (§§ 423.153(f)(5), 423.153(f)(6), §423.38)

(A) Initial Notice to Beneficiary and Sponsor Intent to Implement Limitation on Access to Coverage For Frequently Abused Drugs (§423.153(f)(5))

The Act 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. Medicare Rights supports 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. This should include information regarding how at-risk designations follow individuals through any change in plans, which obviates any need for limitations on SEPs for at-risk or potentially at-risk individuals.

In addition to approving notice language, the Secretary 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. We also encourage CMS to develop language about how to receive assistance from independent sources in addition to the beneficiary's health plan, including 1-800-MEDICARE and the SHIPs.

CMS would also permit the initial notice to be used when the sponsor implements a beneficiary-specific Point-of-Sale (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 steps. It would limit the alarm and confusion a beneficiary might experience if they were to receive an erroneous notice that they may face an interruption or limitation on their needed medications while being, for example, 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 the beneficiary will be truly 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 (§423.38)

CMS proposes to restrict the SEP for individuals who are identified as at-risk or potentially at-risk. Medicare Rights strongly disagrees with this proposal. Beneficiaries who are eligible for both Medicare and Medicaid (dual-eligibles) are afforded the protections of a SEP granted by this status, and we urge CMS not to advance any policy that would limit this protection. Individuals 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 the Act would make a dual-eligible at-risk or potentially at-risk beneficiary ineligible for an SEP. CMS should not add additional “locking in” of the low-income population beyond that contemplated by the Act.

As CMS acknowledges in the definitions for “Potential At-Risk Beneficiary” and “At-Risk Beneficiary,” the statute provides that “at-risk” status is transferable from one plan to another. This means that utilizing the SEP will not allow a given individual to avoid the implications of the lock-in. Since use of the SEP is not limited to (and would not be effective at) avoiding the lock-in provisions, it should not be curtailed. Beneficiaries who are properly informed of this fact would not attempt to switch plans into order to avoid the lock-in and would focus on the most useful appeals strategy—challenging their designation as “at-risk”—rather than changing plans.

(C) Second Notice to Beneficiary and Sponsor Implementation of Limitation on Access to Coverage for Frequently Abused Drugs (§423.153(f)(6))

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 also 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 such an implementation is an at-risk determination that would require two notices as well as appeal rights. We support this change in status for beneficiary-specific POS claim edits to ensure beneficiaries have the information about and protections from this form of limiting their access to medications. We reiterate, however, that the additional “lock-in” of limiting use of the LIS SEP, which is not included in the statute, is not appropriate.

(D) Alternate Second Notice When Limit on Access Coverage for Frequently Abused Drugs by Sponsor Will Not Occur (§423.153(f)(7))

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 believes 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, appeals, and, in extreme circumstances, could even discourage beneficiaries from seeking medical attention.

(E) Timing of Notices (§ 423.153(f)(8))

The Act 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, allowing beneficiaries to be certain of their status without an indefinite risk, 90 days is too long. This is especially true given the proposal above that would curtail the rights of those identified as potentially at-risk 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, that 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 can tentatively support this proposal which would limit the possibility for disruption for the beneficiary. However, the beneficiary must have a clear method to change the pharmacy and/or prescriber since they may have opted to switch plans precisely in order to have access to a different source of care. 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.

Medicare Rights strongly supports 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. 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.

(viii) Provisions Specific to Limitation on Access to Coverage of Frequently Abused Drugs to Selected Pharmacies and Prescribers (§ 423.153(f)(4) and (f)(9) Through (13))

(1) Beneficiary Preferences (§ 423.153(f)(9))

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. Medicare Rights supports disallowing sponsors to lock-in non-network prescribers or pharmacies. However, 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 sections within 14 days of receipt. We support these timelines and notifications.

Beneficiaries must also be able to obtain their prescriptions in the case of 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 (§ 423.153(f)(10))

CMS proposes that plans should only be able to deviate from beneficiary preference upon a strong showing of inappropriate action. Medicare Rights strongly supports this proposal and agrees 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 plan sponsors may have with certain providers and/or pharmacies.

(3) Reasonable Access (§§ 423.100, 423.153(f)(11), 423.153(f)(12))

CMS proposes to interpret the Act 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 business or pleasure. 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 otherwise unavailable.

(ix) Drug Management Program Appeals (§§ 423.558, 423.560, 423.562, 423.564, 423.580, 423.582, 423.584, 423.590, 423.602, 423.636, 423.638, 423.1970, 423.2018, 423.2020, 423.2022, 423.2032, 423.2036, 423.2038, 423.2046, 423.2056, 423.2062, 423.2122, and 423.2126)

CMS proposes to integrate various forms of appeals arising from a beneficiary’s at-risk determination into one appeals process. We support this integration, as it 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 is an infringement on the individual’s status as a fully dual-eligible individual.

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. Medicare Rights strongly opposes the 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 they wished CMS to simply insert this designation into that process. Instead, the Act

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. We regularly receive calls on our national helpline or inquiries on our consumer-oriented website that demonstrate beneficiary confusion about and frustration with the opaque and burdensome Part D appeals process. By forcing beneficiaries who are determined to be at-risk into this deeply flawed process, we 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, Medicare Rights cannot support thrusting additional beneficiaries into this system. Automatic escalation of beneficiary appeals, on the other hand, allows 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.

(x) Termination of a Beneficiary's Potential At-Risk or At-Risk Status (§ 423.153(f)(14))

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.

(xi) Data Disclosure and Sharing of Information for Subsequent Sponsor Enrollments (§ 423.153(f)(15))

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 where incomes are low enough that even minor changes can prove a significant burden or significant advantage.

2. Flexibility in the Medicare Advantage Uniformity Requirements

The Medicare statute requires MA organizations to offer their plans "at a uniform premium, with uniform benefits and level of cost sharing throughout the plan's service area." We encourage CMS to proceed cautiously as it strays from this promise, by waiting until data is collected from existing tests of this flexible model or, at minimum, incorporating the strong consumer protections and oversight present in the model into the broader MA plan landscape.

CMS has historically interpreted the statute as requiring MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. Plan sponsors have asserted that this interpretation of the statute was too narrow and precluded them from offering value-based insurance design (VBID) products that could be used to better address chronic conditions.

In this rule, CMS proposes a change to its previous interpretation of the statute. CMS determined that these statutory provisions permit MA organizations to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same. CMS claims that reviews of plan designs ensure that plan cost-sharing does not discriminate against high-cost beneficiaries. Also, CMS notes that the new flexibility would not eliminate the antidiscrimination provisions which would still prohibit an MA plan from denying, limiting, or conditioning the coverage or provision of a service or benefit based on health status-related factors.

Specifically, "under this new flexibility, MA plans could vary the supplemental benefits, cost sharing for services and drugs, and provider networks for chronically ill enrollees." While we agree, in principle, that

VBID and lower cost sharing to help encourage beneficiaries to seek the most effective care holds promise, we have some significant concerns about implementation under the current proposed regulation.

As CMS notes in the preamble, CMS began to test VBID through the Centers for Medicare and Medicaid Innovation (CMMI) beginning in January 2017. The demonstration program is limited by condition, geography and plan and incorporates significant consumer protections. By proposing to loosen uniformity standards for all plans before the results of that carefully crafted demonstration are understood, CMS is scaling up an experiment before meaningful results are in. CMS should instead learn from the CMMI demonstration, to identify ways flexibility—even for a much smaller cohort with specific conditions—improves health outcomes and strategies to avoid potential pitfalls.

We are also concerned that changing uniformity requirements in the manner CMS proposes could—by itself—create a chaotic environment for Medicare beneficiaries trying to make informed decisions about what options might be best for themselves. A large body of work—including evidence CMS itself cites—has explored the challenges beneficiaries face weighing different coverage options. Weighing the additional variables of different disease-specific offerings will not be feasible for most beneficiaries, even with significant improvements to a Plan Finder tool that currently does not include any of the information that would be relevant to this sort of selection. With this additional flexibility and plan difference, the already challenging process of choosing between various plan options will be even more onerous.

When CMMI first proposed a VBID demo, Medicare Rights and other consumer advocates provided extensive feedback.¹ The resulting demonstration model reflects CMS’s careful consideration of many important beneficiary protections. Such protections, or guard rails, included strong and clear parameters for program design: a multi-stakeholder and transparent process for identifying high-value services and developing conditions of participation; permitting only cost-sharing reductions; limiting or prohibiting advertising and other pre-enrollment marketing of cost sharing adjustments; and opt-in beneficiary selection. Here, CMS proposes to allow alteration of benefits and cost-sharing without regard to the extensive consumer protections included in the limited VBID demo.

As discussed below, should CMS choose to proceed, it must, at a minimum, include basic consumer protections and oversight included in the VBID demo, including the following:

- Set conditions of participation for plans—plans under sanction and plans with below-average star rating should not be permitted increased flexibility;
- Provide support for educational requirements and rigorous evaluation, monitoring, and auditing;
- Utilize only positive reinforcement in the form of lowered cost-sharing and expanded benefits, rather than discouragement of lower-value services (in other words, “carrots” rather than “sticks”);
- Make the rationale for identifying “high-value” care publicly available. At minimum, CMS must vet plan criteria for identifying high-value services, and we urge CMS to make this rationale publicly available, either as part of the demonstration or along with the evaluation of the demonstration. We appreciate that VBID has the potential to enhance health care transparency—both for cost and quality.
- Limit approval of lower cost-sharing only to instances where there is a well-established evidence-base that illustrates a particular service, prescription medication, or health care provider is in fact “high-value.” We also encourage CMS to develop a standardized list of health care services or prescription drugs that may be subject to altered cost-sharing in consultation with clinicians and other experts;

¹ <http://medicarerights.org/pdf/091515-ma-vbid-comments.pdf>

- Ensure that VBID models do not benefit only geographic, economic, or other subsets of MA enrollees;
- Continue extensive evaluation and monitoring. We ask that CMS require reporting by plans, including the number of individuals believed eligible for each supplemental benefit, and the number using each benefit, with a breakdown 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 learn from the data. The financial alignment demonstrations offer lessons learned. To date, there has been very little data reported publicly on supplemental benefits the plans are delivering. Self-reports from beneficiaries have been mixed. Some beneficiaries report increased access to flexible benefits,² 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. Tracking of benefits and outcomes will also allow CMS to evaluate the efficacy of supplemental benefits;
- Disallow marketing to beneficiaries—we strongly support CMS’s approach to limiting plan marketing in the CMMI demonstration. We applaud the agency for its focus on the potential for enrollee confusion and we appreciate the steps proposed to minimize such confusion. Specifically, we endorse the prohibition on the marketing of any VBID program to beneficiaries not currently enrolled in a participating MA plan and encourage CMS to extend these limitations to the benefits allowable under the more expansive reading of the statute. We believe this prohibition reduces the potential for “cherry picking” of prospective plan enrollees and other potentially discriminatory practices. In addition, this prohibition ensures that individuals attracted to a VBID program who are not ultimately eligible (because they do not have the requisite health condition(s) or do not need certain services associated with the VBID program) do not end up enrolled in an MA plan that otherwise might not be the best choice for them. We also encourage CMS to require prior review and approval of all written materials, including scripts for oral communication and distribution plans for materials concerning VBID benefits;
- Improve the Medicare Plan Finder tool—it is absolutely essential that relevant information, including whether the potential enrollee would qualify for the “unique” benefits, what additional or different benefits would be available to them, up-to-date and searchable network information, and other specific information about how the plan would actually work for the beneficiary are seamlessly included in the Plan Finder tool;
- Extend beneficiary and provider education and outreach and develop uniform beneficiary communications and revisit minimum requirements. To promote beneficiary understanding and choice, we encourage CMS to develop and require the use of standardized templates for use by participating MA plans about targeted or unequal benefits. At a minimum, CMS should require that all enrollee communications include plain language information about options, rights, and services in the program. These communications should also direct enrollees to 1-800-MEDICARE and State Health Insurance Assistance Programs (SHIPS) that can help enrollees navigate any confusion or problems with access to care. In addition, we suggest that CMS ensure

² RTI, “Beneficiary Experience: Early Findings from Focus Groups with Enrollees Participating in the Financial Alignment Initiative,” (“Focus Groups”)(March 2017) , available at <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/FocusGroupIssueBrief508032017.pdf>.

all enrollee communications are fully accessible to enrollees and their caregivers. We suggest robust enrollee testing as well as formatting requirements;

- Establish a clear strategy and requirements for health care provider education and outreach. Provider education is just as important as enrollee outreach for ensuring a smooth programmatic rollout. Medicare beneficiaries participate in a complex health care system, within which health care providers largely direct treatment decisions. For VBID and the provision of supplemental benefits to be successful, it must include complementary educational initiatives for both beneficiaries and health care providers. This requires targeted provider outreach that both explains the purpose of the insurance design, as well as addresses providers' practical concerns. We suggest that provider outreach focus on contracting details and include a clear explanation of available benefits and any new billing practices and procedures. We urge CMS to consider outreach to all Medicare providers as well as community based service providers who may interact with enrollees. Recent demonstrations, including the Duals Demonstrations, underscore the importance of ensuring community-based service providers receive outreach and training about new health care systems, as these providers are often the trusted entities beneficiaries turn to with questions;
- Provide enhanced information on 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, including notices that explain the basis for a denial of benefits, and access to a decision-maker independent of the plan.

3. Segment Benefits Flexibility (p. 56361)

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. However, 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.³ 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 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 for plans to communicate, and for beneficiaries to compare and understand, than different premiums and co-insurance.

There are many unanswered questions about how this flexibility would operate across different areas, and this proposed change is a significant one. We suggest that this proposal be tested on a small scale with a few high-performing plans and a limited number of affected beneficiaries. Data issues, Plan Finder issues, broker training, call center training, prior authorization procedures, and many more technical details need to be tested and are essential to beneficiaries successfully navigating this type of plan selection.

4. Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 422.100 and 422.101) & 5. Cost Sharing Limits for Medicare Parts A and B Services (§§ 417.454 and 422.100)

³ 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.

These proposals, which allow greater flexibility to set plan maximum out-of-pocket limits (MOOP) and allow higher cost-sharing limits for services would also, like the uniformity requirements, above, and the meaningful differences between plan offerings, below, add to the challenges Medicare beneficiaries face in making informed decisions about their health insurance coverage. Allowing multiple MOOP levels and increasing the number of service categories that can have higher cost-sharing in exchange for a lower MOOP multiplies the potential variations between and among plans. This will make choosing and understanding plan benefits significantly more complex, especially when such MOOP changes are added to the proposals to loosen uniformity requirements and eliminate meaningful difference requirements. Extensive research and comprehension will be required of anyone wishing to understand exactly what a given plan covers and how much cost-sharing applies.

CMS articulates a “goal of making sure beneficiaries can access affordable and sustainable benefit packages.” To do so, CMS proposes to allow plans to offer higher level MOOP options for lower premiums, but with higher cost-sharing and deductibles. The MOOP is one consumer protection required of MA plans that is absent in traditional Medicare; these proposals seem to dilute this protection. Lower premiums might provide lower ongoing monthly expense, but when a plan enrollee must use services and faces higher cost-sharing and deductibles, the plan is less affordable.

Further, changes to plan MOOP limits can have a differential effect on beneficiaries with varying healthcare needs and costs. While individuals incurring high costs might benefit from plans that offer reduced MOOPs, beneficiaries incurring lower costs may have higher spending on services in plans with a reduced MOOP. Additional oversight is required to ensure that these changes do not contribute to a discriminatory plan design.

6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§ 422.254 and 422.256)

Medicare Rights Center supports CMS’s goal of encouraging competition and plan flexibility. However, while the current use of the out-of-pocket cost model as the only measure of meaningful differences between MA plans is not ideal, we remain very concerned that beneficiaries have more trouble choosing plans when there are many similar plans offered. CMS acknowledges this concern, but asserts that the removal of the meaningful difference standards will not lead to more similar plans being offered. We nevertheless believe that CMS should maintain a quantifiable meaningful difference standard for plan bids.

CMS notes that it “expects” plan sponsors to continue to offer plans that are “different from one another with respect to key benefit design characteristics, so that any potential beneficiary confusion is minimized,” but also suggests that the increased flexibility in plan design will make meaningful difference analysis too difficult—“the current meaningful difference methodology evaluates the entire plan and does not capture differences in benefits that are tied to specific health conditions.” If this analysis will be more challenging for CMS, we are concerned that it will be impossible for beneficiaries.

As the rule states, this change would substantially increase beneficiary confusion. Beneficiaries already face complex choices when shopping for an MA plan; on average, beneficiaries have a choice of 21 MA plans. In 206 counties, beneficiaries chose among more than 30 plans for the 2018 plan year.⁴ CMS suggests this proposal is acceptable because beneficiaries understand the basics of health insurance, but research shows this is not the case. Beneficiaries are more likely to enroll in plans when presented with fewer choices. In multiple studies, beneficiaries had higher rates of enrollment in Medicare Advantage plans when presented with 15 or fewer plans. Empirically, more choice may be detrimental if there are too many or overly complex options, particularly in high-stakes decisions that involve health or money. Beneficiaries may choose inferior options or make no choice at all as a result of cognitive overload,

⁴ Jacobson, G, Damico, A., and Neuman, T. Medicare Advantage 2018 Data Spotlight: First Look. Available at: <https://www.kff.org/medicare/issue-brief/medicare-advantage-2018-data-spotlight-first-look/>

anticipated regret, or bias toward the status quo.⁵⁶ Although a great deal of information is available, beneficiaries often have difficulty understanding its significance and using it correctly to make decisions. Most beneficiaries have difficulty correctly interpreting even simple displays of Medicare health plan information.⁷

The current plan-selection process is not straightforward or easy, and while we strongly urge CMS not to make it more complicated and difficult by removing the meaningful difference standard, we are encouraged that CMS is interested in improving the Medicare Plan Finder tool in an effort to mitigate these problems. Improvements to beneficiary tools to help in coverage selection, including the Plan Finder tool and the Annual Notice of Change (ANOC) are long overdue. We continue to advocate for an individualized MA and Part D ANOC to better serve individual beneficiary needs, and a more responsive Plan Finder tool. The ANOC should include details about which specific providers are leaving a plan network, which specific prescription drugs are no longer on the plan formulary, and where utilization management tools will be newly applied. The Plan Finder must include information about provider networks, office visit and service copays, and coinsurances. These customizations should reflect an individual's actual providers, services, and prescription drugs, especially if, as discussed above, plan services can vary based on health condition.

CMS should consider opportunities to tailor these notices to individual information needs. At a minimum, we suggest that CMS solicit input from multiple stakeholders on recommendations to improve the ANOC, EOC, and other standardized materials used during the annual election period. CMS's commitment to stakeholder input through the comment process for the Welcome to Medicare packet in 2017 was an example of a potential process for modernizing other Medicare notices. It is important to improve all beneficiary decision aids, including mailings and 1-800-MEDICARE, so beneficiaries can more easily use them to understand their choices when shopping for Medicare plan. We are also encouraged to hear of the "new consumer friendly tool for the CY 2018" enrollment period "which will assist beneficiaries in choosing a plan that meets their unique and financial needs based on a set of 10 quick questions." However, such improvements and enhanced tools should be firmly in place and thoroughly tested before other protections, like the meaningful difference standard, are rolled back.

At a minimum, instead of completely repealing the meaningful differences requirement, CMS should propose an alternative test of meaningful differences that may address concerns from plans. CMS could also allow plans to seek waivers by providing alternate evidence of meaningful differences. For example, CMS could require that if the current meaningful difference standard were not met, plan sponsors would have to provide stronger evidence that beneficiaries would be able to easily distinguish between the sponsor's offerings. Applying the meaningful difference standard as leverage would provide CMS with tools to address any confusion.

⁵ *The Evidence is Clear: Too Many Health Insurance Choices Can Impair, Not Help Consumer Decision Making*; Lynn Quincy and Julie Silas; Consumers Union, November 2012 (http://consumersunion.org/wp-content/uploads/2012/11/Too_Much_Choice_Nov_2012.pdf)

⁶ *Cognitive Functioning and Choice between Traditional Medicare and Medicare Advantage*; J. Michael McWilliams, Christopher C. Afendulis, Thomas G. McGuire, and Bruce E. Landon; Health Affairs, September 2011 (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3513347/>)⁷ *Medicare Advantage: Options for Standardizing Benefits and Info to Improve Consumer Choice*; Ellen O'Brien and Jack Hoadley; The Commonwealth Fund, April 2008 (http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2008/Apr/Medicare%20Advantage%20Options%20for%20Standardizing%20Benefits%20and%20Information%20to%20Improve%20Consumer%20Choice/OBrien_Medicare_Advantage_options_1117_ib%20pdf.pdf)

⁷ *Medicare Advantage: Options for Standardizing Benefits and Info to Improve Consumer Choice*; Ellen O'Brien and Jack Hoadley; The Commonwealth Fund, April 2008 (http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2008/Apr/Medicare%20Advantage%20Options%20for%20Standardizing%20Benefits%20and%20Information%20to%20Improve%20Consumer%20Choice/OBrien_Medicare_Advantage_options_1117_ib%20pdf.pdf)

7. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68) & 8. Passive Enrollment Flexibilities To Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (§ 422.60(g))

We appreciate CMS's effort to limit the practice of seamless conversion of beneficiaries. We believe CMS should advance policies that encourage people new to Medicare to make an active and informed choice about the coverage option(s) that are right for them, selecting among Original Medicare, Medicare Advantage plans (including integrated Medicare-Medicaid options), supplemental Medigap policies, and stand-alone Part D prescription drug plans. CMS noted an intention to establish a "simplified election process" for beneficiaries who are not dually eligible, but want to convert their commercial coverage to a Medicare Advantage plan with the same parent organization. We strongly urge CMS to ensure that such an election process relies on clear and complete notice and affirmative selection from beneficiaries.

For individuals in Medicaid managed care plans, the start of Medicare eligibility can lead to more fragmented care, because their coverage of Part A and B services and Part D drugs may now be provided separately, either through FFS Medicare or through MA plans or Part D plans offered by other organizations. In these instances, automatic enrollment into an affiliated D-SNP may promote the use of integrated care (e.g., shared provider networks) by encouraging these beneficiaries to receive both their Medicare- and Medicaid-covered services from the same organization.

However, we strongly believe that CMS should be promoting informed choice wherever practicable. And while 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, 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.⁸ 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 identical to the network in the Medicaid plan.
- Plans should be required to provide transition coverage for providers that are not in the SNP network. Transition coverage provisions in the Medicare-Medicaid financial alignment demonstration contracts provide models, and at a minimum should allow for a beneficiary to maintain an out-of-network provider for twelve months.
- Beneficiaries should have an opportunity to disenroll from the SNP to which they were enrolled by default at any time.
- Default enrollment should not be permitted in service areas where financial alignment demonstrations are taking place.
- The notice process should involve at least two notices.

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

⁸ 82 Fed. Reg. at 56370.

Advantages could apply to so many new beneficiaries that it would threaten the basic clear statutory intent of Section 1851(a) 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 principle.

CMS also proposes 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. CMS envisions that this proposal would apply primarily to individuals in D-SNPs with associated Medicaid managed care plans operated by the same sponsor when 1) the Medicaid managed care plan is no longer contracted with the state, or 2) the D-SNP no longer is contracted with CMS. Under the proposal, these individuals would be subject to passive enrollment to a new D-SNP operated by the same sponsor as the Medicaid managed care plan to which the state has assigned the beneficiary.

We appreciate that the goal of this proposal is to provide continuity to dually eligible beneficiaries affected by contract changes. We also recognize, as CMS has noted, that the number of affected individuals in any year is likely to be relatively small. CMS estimates this affects roughly 22,000 beneficiaries—small relative to the total dual eligible population, but still a significant number.⁹

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

If, however, CMS decides to move forward with passive enrollment, we agree with and appreciate the proposed requirement that the provider network of the new plan be substantially similar to the network of the prior plan. It also is important that prescription drug formularies be 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 are 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 drive Medicare Advantage assignment. For many dual-eligibles, especially those who do not use long-term services and supports, continued Medicare coverage for their prescription drugs and Medicare providers is most important. Access to particular LTSS provider networks may be most important to others. In the design of a passive reassignment program, the state and CMS should work together to ensure appropriate reassignment without automatically prioritizing the state’s Medicaid reassignment decision.

For additional beneficiary protections, we ask for transition policies that allow individuals who are passively enrolled to have a period in which they can continue to see providers who are outside their new network. As has been learned from the dual eligible financial alignment demonstrations, it is important that these policies be easy for beneficiaries and providers to navigate.¹⁰

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.

⁹ 82 Fed. Reg. at 56434.

¹⁰ Focus Groups, *supra* note 5, finding that beneficiaries lacked awareness of transition protections, mainly due to the complexity of the information provided upon 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:¹¹

- 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.¹²

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.¹³

9. Part D Tiering Exceptions (§§ 423.560, 423.578(a) and (c))

Medicare Rights appreciates CMS's commitment to clarifying the tiering exceptions process, and thus finding solutions to provide lower cost-sharing for beneficiaries taking expensive therapies. Medicare Rights encourages CMS to explore other solutions to reduce the out-of-pocket burden facing these beneficiaries utilizing specialty tier drugs, including: 1) performing more stringent discrimination review to ensure that certain classes of drugs are not always placed on specialty tiers; and 2) allowing cost sharing exceptions for specialty tier drugs.

We also encourage CMS to provide more education to beneficiaries regarding options for tiering exceptions. Very little information exists for beneficiaries, and what information beneficiaries have is difficult to understand and apply to individual situations. Forms of 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.

¹¹ 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.

¹²

¹³ 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](https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/MultistateIssueBriefFAI.pdf).

10. Establishing Limitations for the Part D Special election Period (SEP) for Dually Eligible Beneficiaries (§ 423.38)

CMS proposes to restrict the SEP for all individuals who are dually eligible beneficiaries. Medicare Rights strongly disagrees with this proposal. We urge CMS not to advance any policy that would limit this vital consumer protection. While CMS's proposal would still allow dually eligible beneficiaries at least one annual SEP, some beneficiaries require multiple changes in their plans throughout the year because of changes to their own medical needs, including new medications, or because of other changed circumstances or preferences, including changes to their plan's formulary or provider network. The ability of this vulnerable group to choose plans and best manage their care should not be limited.

As CMS acknowledges, very few people use the SEP for dually eligible beneficiaries multiple times in a year. While CMS implies both that this is because most eligible beneficiaries do not need to change plans mid-year, and that a beneficiary's ability to change plans inhibits the plan's ability to provide good case management and customer service, our experience is different. Through our work with thousands of beneficiaries on our National Consumer Helpline, we regularly hear from beneficiaries eligible for this SEP, who would benefit from changing plans, but do not realize they are eligible for an SEP. We routinely receive calls from low-income beneficiaries whose plans do not cover the medications they need, who face onerous utilization management requirements, or cannot receive the medical services they need through their current plan. In most of these cases, the plan is not providing good case management—the beneficiary is confused, frustrated, and may be paying out of pocket or going without essential medications. In a large number of these cases, the beneficiary is switching between PDPs, so there is no impact on case management or care delivery.

Currently, we are able to assist these beneficiaries—even if they had recently enrolled (or been automatically enrolled) in the plan. With any of the discussed alternatives to the current SEP, some of these beneficiaries would be locked in to plans that are unaffordable or do not meet their medical needs.

All of the alternatives to the current once-per-month SEP right would leave behind an extremely vulnerable population who often lack the health insurance literacy necessary to know that some of the problems they are facing might be addressed by utilizing their rights under the LIS-SEP. Medicare Rights recognizes the challenges that plans face in providing case management to individuals who may switch plans mid-year, where another plan may see the savings related to improved health because of increased medication adherence. Given, however, the infrequency of the utilization of the SEP, however, and based on the experiences of our helpline callers, we encourage CMS to enhance, rather than restrict, the LIS-SEP, by providing improved educational materials to those who are eligible for the SEP.

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.

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

We strongly urge CMS maintain the continuous SEP for dual eligibles and LIS beneficiaries. It is an important beneficiary protection that is simple to understand and implement. The narrow and discrete

issues that have arisen with respect to duals enrollment can better be addressed by more targeted measures that do not impose limitations on the entire LIS population.

If, however, CMS moves forward with the proposal, we request that CMS amend the current language, which treats a decision to opt out of an auto enrollment, facilitated enrollment, passive enrollment, default enrollment or reassignment as using up a SEP.¹⁴ 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.”¹⁵ 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.

11. Medicare Advantage and Part D Prescription Drug Program Quality Rating System

b. Background

CMS solicits feedback on how well the existing stars 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. Medicare Rights continues to support CMS’s 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 MA 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 very highly reflected 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 pose a serious threat to the health and safety of Medicare beneficiaries, that finding must have an impact on overall ratings.

f. Contract Consolidations

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

¹⁴ 82 Fed. Reg. at 56374.

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

Medicare Rights supports 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

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 the programs have to respond to the changing landscape of quality measures. While CMS rightly suggests that the universe of quality measures has matured somewhat, Medicare Rights believes 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

CMS appears to propose to increase the weight of patient experience/complaints and access measures to 3 or nearly 3. Medicare Rights supports 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

CMS proposes to stratify quality measure reporting by demographic data such as dual eligibility or low income and disability status. Medicare Rights supports 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

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.

12. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (§§ 423.100, 423.505)

(a) Clarification to "Any Willing Provider" Requirements

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

willing provider” requirement to all pharmacy business models, including those with multiple lines of business.

(b) Definition of “Mail-Order Pharmacy” and “Retail Pharmacy”

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

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

14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)

CMS proposes to allow plans greater flexibility for generic substitutions. Specifically, plans could immediately—any time of year, 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. The proposal suggests that plans could provide beneficiaries with a generalized advance notice (warning beneficiaries that such substitutions could happen), and then provide retrospective notice on the specific changes.

We strongly oppose this change. The current 60-day notification allows the beneficiary time to understand how a generic drug would affect their treatment regimen. Without notification, a change in cost sharing and the pill size, shape, and color would cause undue stress on beneficiaries, regardless of whether their treatment regimen could withstand a change to generic drugs. This in turn could affect adherence and health status.

Furthermore, we are concerned by CMS’s statement that advanced notice is unnecessary because no enrollee could show that they would “be better served by taking no medication rather than the generic unless he or she had previously tried the generic drug.” Not only is this standard—that a person would have to be better served taking no medication rather than the plan-preferred alternative—not the standard for a plan to be required to provide a formulary exception or an exception to a step therapy restriction or non-preferred tier, but it is also inaccurate to represent that a person must always “try” an alternative before an exception can be or must be provided. Indeed, Medicare Rights has worked with many beneficiaries whose providers had sound medical reasons for believing that a particular alternative would not be as effective or would cause the beneficiary harm to obtain coverage for essential medications. CMS should clarify that this statement is not consistent with any appeals standards.

15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

Medicare Rights supports CMS’s 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 spur greater price competition among biological products, expand access for beneficiaries, and help to restrain growth in program spending.

16. Eliminating the Requirement To Provide PDP Enhanced Alternative (EA) to EA Plan Offerings With Meaningful Differences (§ 423.265)

Medicare Rights supports CMS's goal of encouraging competition and plan flexibility in Part D. However, we are concerned about the removal of the meaningful difference requirement in Part D. As we explained in our comments for Part C, we believe the use of an objective, quantifiable measure can provide valuable information to beneficiaries when evaluating plan options that have different benefit designs (and to the agency during the bid review process). CMS could 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 difference 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 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's 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.

Risk segmentation is counter to the notion of insurance policy and could be a concern for the program, particularly if it involves avoiding LIS enrollees.¹⁶ By enrolling healthier beneficiaries into certain enhanced plans, plan sponsors may segment higher cost enrollees into plans with higher premiums for basic benefits. To the extent that the basic plan qualifies as an LIS benchmark plan, it could increase the amount Medicare pays for the low-income premium subsidy. Given this potentially adverse impact on the program, we believe it is important to continue to distinguish between basic and enhanced plans.

17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

Medicare Rights generally supports CMS's proposal to pass through a percentage of manufacturer rebates and pharmacy price concessions to drug prices at the point of sale, as we support all efforts towards greater price transparency. We remain concerned that separate treatment of direct and indirect remuneration (DIR) can distort beneficiary and plan decision-making. A November 2016 Milliman report concluded that Part D plans have a financial incentive to cover drugs with higher list prices and higher rebates, compared to lower price drugs with lower rebates.¹⁷ Moreover, because benefit designs have shifted more to coinsurance for brand drugs (based on the list price), beneficiaries who take medications with high rebates are not benefitting financially from those higher rebates. Thus, the current process results in increased costs to both the government and beneficiaries.

In January 2017, CMS also released a memorandum examining direct and indirect remuneration (DIR) in Part D, which reached the same conclusion.¹⁸ In that report, CMS notes that DIR increases do not result in lower Part D plan premiums, even though plans have been required to pass rebates through to

¹⁶In 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.)

¹⁷Barnhart, AJ and Gomberg J. Financial incentives in Medicare Part D. The AIDS Institute. Available at <http://theaidsinstitute.org/sites/default/files/attachments/Milliman%20Report%20-%20Final.pdf>

¹⁸Centers for Medicare and Medicaid Services. Medicare Part D-direct and indirect remuneration. Available at <https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html>

beneficiaries in the form of lower premiums. The fact that the incentives of Part D allow and, even encourage, a system of drug pricing and rebating that disguises true prices and shifts spending to beneficiaries and the federal government concerns us. By passing through a percentage of rebates and pharmacy price concessions to beneficiaries at the point of sale, CMS can work towards achieving the important goal of price transparency for beneficiaries.

Of course, projected premium increases are also concerning. CMS should determine the percentage of rebates and pharmacy price concessions to pass through using a strong evidence base so as to increase transparency without large increases to premium rates. We understand that premiums are set according to a multifactorial process and various factors can and will influence average premiums, so we encourage CMS to closely monitor premiums and other Part D plan components and make appropriate changes if necessary.

It is important to note that while this proposal will hopefully lead to lower cost sharing for some beneficiaries, it does not solve the larger problems with drug pricing. Medicare Rights encourages CMS to work to develop strategies to address the high costs of prescription drugs faced by beneficiaries and the program as a whole.

B. Improving the CMS Customer Experience

4. Revisions to Timing and Method of Disclosure Requirements (§§ 422.111 and 423.128)

Medicare Rights 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.

However, we are concerned about the proposal to increase electronic delivery of important beneficiary documents, by requiring beneficiaries to opt out of electronic delivery if they want a paper copy of certain items. According to a recent Pew study, only half of older adults have broadband at home, and a third of older adults don't use the internet. Access to broadband and usage of the internet also varies with age, even among older adults. Technology usage decreases substantially above the age of 75. Technology adoption also varies substantially with income. For example, while 87% of seniors earning more than \$75,000 per year have broadband at home, only 27% of seniors who earn less than \$30,000 per year have access to broadband at home. Further exacerbating these issues is the level of confidence older adults have in technology. For example, 34% of those who do use the internet report having little or no confidence in their ability to perform online tasks.¹⁹

We appreciate the interest in going paperless and support an eventual move in this direction, when more of the population has access to reliable, affordable, fast internet and the printing and record keeping facilities needed to maintain necessary information. To encourage fewer paper deliveries, CMS should instead allow beneficiaries to opt-in to electronic delivery.

We also would like to reiterate the importance of continuing to send the ANOC, as well as all explanations of benefits (EOBs) and appeals information as a paper document. This is one of the most important documents beneficiaries have for making informed decisions about their coverage for the upcoming year, and it is imperative that all beneficiaries continue to have easy access to the document.

5. Revisions to Parts 422 and 423, Subpart V, Communication/Marketing Materials and Activities

¹⁹ Pew Research Center, May 2017, "Tech Adoption Climbs Among Older Adults."

We appreciate the need to appropriately classify materials for marketing purposes or otherwise. However, we are concerned that many materials which need oversight by CMS, regardless of their classification, would not have rigorous oversight under this proposal. CMS needs to maintain standards for all documents that target beneficiaries, whether they involve marketing, education, or another type of communication. Beneficiaries need to make informed decisions not just about enrollment, but about maintaining enrollment and using their insurance benefits in the health care system.

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 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, etc. An expansion of translated documents is long overdue expansion and 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 addressing 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. Including numerical as well as percentage thresholds would lead to more rational results, particularly for PDPs that serve large populous states.

6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (§§ 423.590 and 423.636)

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. Given that many Medicare beneficiaries are on limited budgets (e.g., on average, Social Security benefits account for more than 60 percent of income for seniors; for more than one-fifth of seniors, Social Security benefits account for 100 percent of income), we are concerned about the increased financial burden this proposal would place on enrollees. 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.

7. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE (§ 422.590)

Medicare Rights does not support CMS's proposal to eliminate the MA plan notice for cases sent to the IRE in an appeal. 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, which is unknown to them. Thus, eliminating this notice could lead to beneficiary confusion about the status of their appeal. If CMS wants to limit duplication of effort, it would be better to delay the point at which the IRE sends a notice to beneficiaries.

B. Proposed Provisions

(2) Targeted Approach to Part D Prescribers

CMS proposes to rescind the current provisions that require physicians and eligible professionals to enroll in or validly opt-out of Medicare for their Part D drug prescriptions to be covered by Medicare. CMS proposes, instead, to create a "preclusion list" which would name prescribers who are not permitted to participate in the Medicare program because of conduct that is detrimental to the best interests of the Medicare program. Medicare Rights has some concerns about this proposal. While it is clear that the implementation of enrollment for Part D prescribers has been very challenging and has not yet gone into effect, the process of applying for enrollment and subsequent enrollment allows CMS to investigate and curtail problematic prescriber enrollments before they occur. This proactive approach would create the most secure atmosphere for beneficiary safety and wellbeing while protecting the Medicare program from the fraud and abuse identified by CMS as the prime driver of the previous requirement. Reactive provisions such as a preclusion list must always lag behind proactive provisions such as enrollment requirements. CMS proposes to assess providers based on the risk to Medicare beneficiaries and only focus on those who pose an elevated risk, but identifying those who pose an elevated risk is the very purpose of an enrollment process. CMS's proposal, then, may put beneficiaries at risk for inappropriate prescribing practices from physicians and eligible professionals who would not have successfully completed the enrollment process.

Instead of switching to this reactive preclusion list, we encourage CMS to proceed with enrollment requirements with realistic timeframes, comprehensive outreach plans, and beneficiary financial protections during the transition.

(3) Provisional coverage

CMS proposes to prohibit plan sponsors from rejecting claims or denying beneficiary requests for reimbursement for a drug on the basis of the prescriber's inclusion on the preclusion list, unless the sponsor has first covered a 90-day provisional supply of the drug and provide individualized written notice to the beneficiary that the drug is being covered on a provisional basis. While we appreciate this effort to ensure that beneficiaries are not put at risk by bad-faith physicians and eligible professionals, and we support this restriction if the preclusion list is implemented, it is a clear demonstration that any reactive preclusion list must lag behind proactive approaches like enrollment requirements.

11. Preclusion List—Part C/Medicare Advantage Cost Plan and PACE Provisions

B. Proposed Provisions

CMS proposes to rescind the current requirement that providers or suppliers who can enroll in Medicare must enroll to provide health care items or services through an MA organization. CMS proposes, instead, to create a "preclusion list" which would name individuals or entities who are not permitted to participate in the Medicare program because of conduct that is detrimental to the best interests of the Medicare program. We have significant, pressing concerns about this proposal. While the Part D enrollment process as discussed above has not yet gone into effect, the Part C process has already been implemented. By switching at this late date from a proactive enrollment process which best protects beneficiaries and the

Medicare program from the fraud and abuse identified by CMS as the prime driver of the previous requirement, CMS is proposing to take a step back in time.

Instead of dismantling the enrollment requirements which CMS identified as the best way to ensure health services through MA organizations are provided by qualified providers and suppliers, CMS should keep those requirements in place and step up outreach to those who could have enrolled but have not. This proactive, not reactive, process is the superior option for protecting beneficiaries and the program itself.

C. Implementing Other Changes

b. Proposed Regulatory Changes to the Calculation of the Medical Loss Ratio (§§ 422.2420, 422.2430, 423.2420, and 423.2430)

(1) Fraud Reduction Activities

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

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

(2) Medication Therapy Management (MTM) (§§ 422.2430 and 423.2430)

CMS also proposes to include Medication Therapy Management (MTM) activities as Quality Improvement Activities. CMS currently requires MTM benefits and includes MTM measures in star ratings. CMS also believes that MTM programs improve quality and care coordination for Medicare beneficiaries. We agree. The purpose of the MLR is to require insurers to benefit consumers and improve clinical services and health care quality. MTM programs have the potential to improve the care that beneficiaries receive and plans may be incentivized by their inclusion as Quality Improvement Activities under the MLR rules. Thus we support their inclusion.