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April 6, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via [regulations.gov](https://www.regulations.gov)

RE: CMS-4190-P

Dear Administrator Verma:

AARP, on behalf of our nearly 38 million members and all older Americans nationwide, is pleased to submit the following comments on the Proposed Rule for the CY 2021 and 2022 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-For-Service, Medicare Prescription Drug Benefits, and PACE programs.

We are committed to ensuring older Americans have affordable access to high-quality, high-value health care. In particular, we have worked to improve access and quality in Medicare and Medicare Advantage (MA), and to ensure the beneficiary's perspective is part of care delivery. We continue to support many elements of the proposed rule, including the use of telehealth to increase access to services and providers, the alignment of Medicare and Medicaid to better coordinate care and simplify access, and increased access of high quality and affordable health care.

Supplemental Benefits

AARP recognizes that the bipartisan Budget Act of 2018, as well as recent CMS guidance, has provided insurers new options to offer supplemental benefits. As a result, MA insurers can now cover a much wider array of supplemental benefits and have greater flexibility to design and tailor those benefits for individuals (e.g., support for family caregivers, in-home supportive services, benefits to address social determinants of health).

Experts have long recognized that people's medical conditions and health outcomes can drastically improve with certain types of non-medical support, such as long-term services and supports, family caregiver support services, and other interventions that address social determinants of health. The new rules could incentivize plans to adopt a more inclusive view of what matters to MA enrollees' health. One important potential aspect insurers could address is support for family caregivers – helping people who are instrumental in keeping older family members out of hospitals and nursing homes.

However, we caution CMS to carefully monitor potential new challenges that the policy changes could bring about for Medicare beneficiaries. The availability of new targeted benefits that are primarily health-related and new targeted Special Supplemental Benefits for the Chronically Ill (SSBCI) could very likely become confusing for enrollees. For people struggling with health conditions, poor plan communications that confuse rather than illuminate are likely to make it more difficult for individuals to determine eligibility for supplemental benefits and whether specific plans are the best choice for their individual needs.

AARP encourages CMS to make available detailed guidance addressing transparency in marketing and communications related to primarily health related supplemental benefits and for SSBCI under BBA 2018. We believe that clear and strong communication will be key to the success of these benefits flexibilities. Enrollees should be provided with information that describes in simple and understandable terms when new benefits based on a person's health conditions are available and when they are not available. These communications should be made both at enrollment as well as upon request after enrollment. Transparency at enrollment is important to ensure that beneficiaries choose a plan based on an understanding of the benefits available to them. For example, if plans market benefits to all enrollees that are only available for individuals with certain health conditions, it will not only cause confusion but could result in people making poor plan choices for their own situations.

In addition, we urge CMS to monitor carefully to ensure that insurers do not market or implement the new flexibilities in ways that result in the segregation of higher-risk individuals from lower-risk individuals – leaving less healthy and more costly beneficiaries with fewer coverage options. CMS should:

- Increase oversight of non-discrimination requirements to ensure that insurers do not use new supplemental benefit flexibility to design plans in a discriminatory manner, attempt to attract more financially advantageous enrollees, or steer enrollees into certain plans.
- Ensure that MA plans use new supplemental benefit flexibility to provide meaningful coverage and such benefits are not simply used as a marketing advantage to attract additional enrollees.
- Encourage insurers to offer supplemental benefits that are informed by best practices (e.g., from Medicaid managed care) or that have been shown to improve care and health outcomes in other settings, such as support for family caregivers.
- Provide marketing and advertising guidelines to ensure that plan marketing materials minimize consumer confusion and clearly specify which enrollees are eligible for new supplemental benefits and provide clear information about limitations on such benefits, including that benefits may change annually.

- Ensure that State Health Insurance Assistance Programs (SHIPs) and other trusted sources for Medicare beneficiaries have the necessary information to answer consumers' questions about changes to supplemental benefits, and ensure that information about supplemental benefits are not oversold and are presented with appropriate limitations on the Medicare Plan Finder.
- Adopt similar innovations within traditional Medicare to encourage access to comparable benefits for all Medicare beneficiaries.

Implementation of the Opioid Provisions under the SUPPORT Act

In general, AARP supports CMS codifying provisions of the SUPPORT Act to ensure that Drug Management Programs (DMPs) are adopted by all MAPD and Part D plan sponsors and to increase access to those programs for beneficiaries who are potentially at risk of opioid-related substance use disorders. We offer the following specific comments on CMS' proposals:

Requirement that plan sponsors adopt DMPs. CMS proposes to codify Section 2004 of the SUPPORT Act to require, beginning January 2022, Part D sponsors to adopt DMPs. DMPs rely on electronic databases to collect and analyze data on drug prescribing and dispensing in order to avoid potential drug interactions and reduce overprescribing and doctor shopping. The preamble indicates that this requirement would be codified in 42 CFR Section 423.253(f) but the proposed revision does not appear in the proposed regulatory text. We support the intent behind this provision but request that CMS provide the proposed language for comment and review.

Definition of "Potential At-Risk Beneficiary". AARP also supports CMS' proposal to incorporate in the definition at §423.100 of a "potential at-risk beneficiary" individuals with a history of opioid-related overdose. Those individuals would be described as including people meeting two conditions: (1) the individual has at least one recent Medicare fee-for-service (FFS) claim containing a principal diagnosis of opioid overdose and (2) the individual has at least one recent prescription drug event (PDE) for an opioid medication.

We believe that the regulatory text should be clarified to make clear that both of those conditions must be met for a person to be identified as a potential at-risk beneficiary. The interpretation that both must be met in this summary is based on the description in the preamble, but the regulatory text is unclear. We would oppose describing a potential at-risk beneficiary as a person who meets one OR the other of those two conditions, as we do not believe that a single PDE for an opioid medication is enough to designate an enrollee as a "potential at-risk beneficiary." CMS should make the regulatory language consistent with that principle.

Eligibility for Medication Therapy Management Programs (MTMPs). Section 6064 of the SUPPORT Act added a provision requiring that, beginning January 1, 2021, "at-risk beneficiaries" be targeted for enrollment into plans' MTMPs. In general, MTM services are targeted to beneficiaries who meet certain eligibility criteria. Under existing rules, plans can identify their own criteria for whom to target for the MTM program as long as they include beneficiaries who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur Part D costs in excess of a specified cost threshold.

In general, AARP supports the services available to beneficiaries under MTMPs and believes that “at-risk beneficiaries” could benefit from such services.

Suspending Pharmacies Where There are Credible Allegations of Fraud or Program Integrity Concerns. AARP supports CMS’ proposals to codify provisions of the SUPPORT Act that would strengthen program integrity, improve the identification of credible allegations of fraud, and to better share information about providers who engage in suspicious activities including inappropriate prescribing of opioids.

AARP has a long history of encouraging proposals that reduce waste, fraud and abuse. We are particularly concerned about responsible prescribing of painkillers and support the new statutory provisions to help Medicare plans better respond to, detect and reduce or eliminate problematic behaviors.

We encourage CMS to finalize its proposals to permit plans to suspend pharmacies based on credible allegations of fraud, inappropriate prescribing, and “substantiated or suspicious activities of fraud, waste, or abuse.” We believe the proposed changes would add clarity and provide tools for plans to respond to allegations of over-prescribing.

Further we support codifying proposals that ensure information is made available to CMS and from CMS to plan sponsors via secure data sharing. We believe improved transparency related to activities and trends in identifying suspicious prescribing activity and opioid overprescribing is necessary. However, we strongly urge CMS to undertake these activities with considerable care and nuance to help ensure that tips are verified before they are used to suspend activity of a provider or prescriber. CMS should also monitor the implementation of this proposal to ensure that monitoring and penalties do not encourage providers to be unnecessarily conservative when prescribing opioids, potentially limiting access for older adults with legitimate medical needs.

Permitting a Second “Preferred” Specialty Tier

In the preamble of the proposed rule, CMS describes a proposal to permit a Part D plan to have up to two specialty tiers. The regulatory language to do so, however, does not appear in proposed regulatory text. AARP encourages CMS to provide the proposed regulatory language for review and comment before finalizing the provision.

Broadly speaking, AARP supports efforts to improve the ability of health plans to negotiate with drug manufacturers, including high-priced specialty drugs. Assuming this proposal moves forward, Part D program and enrollee costs could be reduced if Part D plan sponsors use their second specialty tier to encourage greater use of less expensive biosimilars and greater price competition for specialty drugs.

We also believe that the full benefits of this policy can only be realized if enrollees have access to a meaningful exceptions and appeals process. We have previously recommended that CMS evaluate and improve these processes to help ensure that they are not too complicated or cumbersome for enrollees to successfully navigate.¹ Appeals processes must be transparent,

¹ <https://www.aarp.org/content/dam/aarp/politics/advocacy/2018/07/aarp-drug-blueprint-rfi-comments-071618.pdf>

easy-to understand, and fair in order for them to function as a true recourse. HHS should also be willing to regularly revisit and make changes to these processes as necessary to ensure beneficiary access. Further, any beneficiary notices should be clear and understandable, and timelines for responding to enrollees should be as short as warranted by the beneficiary's medical situation.

In addition, we support CMS' proposal to update specialty tier thresholds annually rather than keep those amounts at the 2017 level indefinitely. By not regularly updating the specialty tier threshold amount, the number of drugs that could qualify as a specialty drug has increased over time. Specialty drugs currently do not qualify for tiering exceptions under Part D, limiting enrollees' ability to reduce what is often substantial cost-sharing.

Beneficiary Real Time Benefit Tool (RTBT)

AARP applauds CMS' proposal to require plan sponsors to provide beneficiaries with a RTBT to provide timely, clinically appropriate, patient-specific formulary and benefit information in a beneficiary-specific portal or computer application. AARP strongly supports efforts to ensure that Medicare beneficiaries are provided with information about cost sharing and the availability of lower cost alternatives. In addition to those two types of information, the RTBT would also provide information on the formulary status for prescription products as well as utilization management requirements for each alternative.

We believe that having this type of information in real time would be very helpful to enrollees at all points but especially at the point of prescribing. It would permit patients and their prescribers to make better informed decisions about treatment options and by providing formulary status and utilization management requirements, it could help reduce the amount of resources devoted to responding to coverage restrictions.

CMS suggests but does not codify that a sponsor's Pharmacy & Therapeutics (P&T) Committee could evaluate which alternative medications could be excluded, including those: 1) with significant negative side effects, 2) considered to be "drugs of last resort," 3) contra-indicated because of interactions with other drugs that the beneficiary is using, or 4) for other clinically-appropriate instances. Alternatives may only be excluded based on clinical appropriateness and not based on cost. Otherwise, the medication options that would be provided through RTBTs is left up to plan sponsors. Also in preamble but not in regulatory text, CMS indicates that a beneficiary must be provided with a prominent notice that they have received a curated list of options.

CMS does not require, but encourages, plans to include a drug's negotiated price in addition to the beneficiary's out-of-pocket costs (or alternative information that allows the beneficiary to view the comparative plan costs). AARP supports both of these proposals. In addition, AARP provides the following recommendations for CMS as it begins to develop applicable regulations and guidance for required RTBTs. CMS should:

- Ensure that beneficiary education and outreach efforts include information that will help beneficiaries understand and use the information that would be available via the RTBTs.

- Ensure that RTBTs are user friendly and the information that is provided is easy for beneficiaries to understand.
- Ensure that the information provided to beneficiaries is consistent with the information provided to their providers through provider-RTBTs, as required in last year's rulemaking.
- Require plans to develop careful, evidence-based policies for excluding certain alternatives from the RTBTs. Related criteria should be based on clinical evidence.
- Require plans to clearly convey when beneficiaries are receiving a curated list.
- Carefully monitor the alternative drugs that plans choose not to include in RTBTs and penalize plans that inappropriately exclude treatment options.

Telehealth

In response to CMS' solicitation of feedback on a potential future regulatory change to eliminate the existing requirement that plans offering additional telehealth benefits may only do so through contracted providers, AARP supports this possible future regulatory change. We believe that telehealth coverage should be more available in general. Telehealth coverage has been significantly increased as our nation battles the COVID-19 pandemic, and we encourage CMS to continue making improvements, such as opening network requirements for appropriate providers.

AARP strongly supports improvements in access to healthcare services and providers that we believe would come from expanding the use and availability of telehealth services. Medicare enrollees in rural areas, other underserved areas, and those who are home-bound can especially benefit from expanding access to telehealth providers and services. Telehealth can also help to increase access in geographic areas and for specialties where access is limited because too few providers are available.

However, expanded use of telehealth should be closely monitored to ensure that it improves health care quality without unnecessarily increasing costs to the Medicare program. We believe CMS should take care, through oversight, to ensure that telehealth is used to maintain a high quality of care – and not be used as merely an administratively cheaper alternative.

We also encourage a high level of communication and transparency to ensure that enrollees understand when they have a choice of receiving a service in person or via telehealth. Further, to ensure that enrollees are well-informed about the providers and the telehealth services that are available to them, each enrollee should be advised about their choice of receiving a service at a physical location or via telehealth.

Consumers should be made fully aware of new telehealth benefits available to them, but in a way that does not worsen the already daunting task of shopping for and navigating MA plans' benefits, especially at a time when consumers are already trying to navigate new changes to supplemental benefits and Medicare's shopping tools.

Finally, while we are pleased with the progress in access to telehealth services for beneficiaries enrolled in MA plans, we strongly urge CMS to ensure that similar improvements in access to

telehealth services are provided to beneficiaries enrolled in fee-for-service Medicare. Beneficiaries enrolled in traditional Medicare should be able to benefit from the same innovative services that could help patients and providers alike. Telehealth can improve access to care, especially for rural beneficiaries and those who cannot travel to a provider's office or facility. While many restrictions have been relaxed during the COVID-19 pandemic, these are temporary improvements in traditional Medicare and MA still has greater flexibility in offering services. We urge CMS to use its authority to explore and implement new ways that traditional Medicare could benefit from similar innovative services.

MA & Part D Prescription Drug Quality Rating System

AARP appreciates CMS' ongoing efforts to ensure that the Star Ratings system is continually improving. We appreciate that CMS is continuing to refine the system by adding, removing, and updating measures, by revising cut point methodologies for certain measures, and by revising measure scores where there is a contract consolidation. These updates altogether help to ensure that the quality rating system is patient focused, and is helping to guide beneficiaries to find the best plans and providers. Meaningful, accurate, and reliable information about quality and costs are essential to empowering beneficiaries and actively engaging them to make the best choices for their own health care.

Medical Loss Ratio (MLR)

AARP does not support the proposal to provide an adjustment in the MLR formula for MA medical savings account (MSA) plans. Under the proposal, CMS would increase the applicable MLR based on increasing levels of deductibles, which would encourage more MA MSA plan offerings as their MLRs are easier to achieve.

We do not support policies that single out high deductible plan offerings for preferential MLR treatment to encourage more Medicare beneficiaries to shift to high deductible health plans. Because of the lack of predictability of health care, especially among the elderly population, Medicare should not encourage beneficiaries to rely upon MSAs to cover an individual's health care expenses as well as high deductibles. Research suggests that people subject to high deductibles may feel financial pressure to avoid needed health care, resulting in potentially even higher costs down the road. In addition, most elderly persons -- especially those with chronic or disabling health conditions -- are far less likely to save as much as younger, healthier people.

Reconsideration and Redeterminations Processes

AARP appreciates CMS' proposals to codify, clarify and to make consistent certain procedures related to redetermination and reconsideration requests. We support proposed new policies to permit an enrollee (or other party) to request an IRE review of an MAO's reconsideration and to establish a process for enrollees to request IRE review of a Part D plan sponsor's dismissal of redetermination requests. We agree that these policies address certain inconsistencies in the system and have increased confusion for enrollees and their providers.

AARP and others have long raised concerns with the exceptions and appeals processes under the Part D program, which are time consuming, frustrating and burdensome for many individuals. We appreciate CMS addressing some of the existing gaps in the processes that have caused confusion for enrollees and plans. Exceptions and appeals processes should be transparent, easy to understand, and fair in order for them to function as a true recourse. We encourage CMS to regularly revisit and make changes to these processes as necessary to ensure beneficiary access.

Network Adequacy Maximum Time and Distance Standards

CMS proposes to codify its network adequacy rules, base standards and methodologies that have in the past been communicated through sub-regulatory guidance. CMS would include a table identifying the 27 provider specialty types and 14 facility specialty types that would be subject to base time and distance standards and the applicable standards in each of 5 different types of counties. Included in these provisions are proposed changes to reduce the percentage of beneficiaries in certain rural counties that a plan must ensure live within minimum time and distance standards, a proposal to loosen network adequacy requirements to reward plans that provide telehealth services for certain specialties, and to loosen standards for plans in states with certificate of need statutes. AARP makes the following recommendations for specific sections below:

Credit for Beneficiaries Affected by State Certificate of Need (CON) Laws. CMS is proposing MAOs receive a 10-percentage point credit towards the percentage of beneficiaries meeting time and distance standards for any affected provider and facility types in states with CON laws *or other state-imposed anticompetitive restrictions that limit the number of providers or facilities in a state.* The purpose of this credit would be to account for the adverse effects that CON laws have on access.

AARP requests that CMS define what is meant by “other anticompetitive restrictions” that could qualify a plan for the 10 point credit. We also recommend CMS clarify the conditions for which the credit would be available. We find it concerning that network adequacy standards could be reduced based on unspecified conditions and fear that different administrators could have widely different interpretations of that term, resulting in uncertainty about network adequacy requirements and potential reductions in access to providers for MA enrollees.

Rewards & Incentives (R&I). CMS proposes to codify and clarify existing guidance on the use of rewards and incentive programs. Among the proposals would be provisions intended to ensure that R&Is are not used to discriminate against enrollees. We strongly support CMS actions to ensure that R&Is are not designed or used in ways that permit discrimination. CMS should also ensure strong enforcement, and if programs are found to have a discriminatory impact, they should be swiftly halted and plans held accountable. In addition, since evidence on R&Is are relatively new, if they are found to cause problems, CMS should have the ability to quickly halt the program and re-evaluate. If implemented, R&Is should be uniformly offered to any qualifying individual, provide accommodations to those who are unable to perform the target activity in a manner that satisfies the intended goal of the target activity, and should not be designed to be based on the achievement of a health status measurement.

Requirements for Medicare Communications and Marketing. In response to CMS' request for guidance on how it should implement prohibitions on plan marketing during the open enrollment period, AARP strongly recommends that CMS ensure that MA plans are not provided with any additional promotion advantages relative to Medicare fee-for-service during the open enrollment period.

We support enabling Medicare beneficiaries to make their own best choice between MA and traditional Medicare based on their own health care needs, preferences, and history. While we support plan choice, for many individuals an MA plan may not be the right choice. Some individuals may not be able to continue with their current medical providers if they were to join an MA plan. Others may be concerned that a plan's prior authorization rules could impact their ability to access needed services or medications. For individuals with long-standing health care relationships or with chronic health care needs, MA plans may not be the best choice and should not be promoted unfairly.

The MA program also has a history of marketing abuses involving enrollment. As such, CMS should maintain strong marketing prohibitions during open enrollment in order to protect beneficiaries. Individuals can best make good enrollment decisions if they are presented with balanced neutral information. Plans should not bombard individuals with unsolicited marketing, especially once they have made their initial enrollment choice not to enroll in an MA plan.

Lastly, CMS should more effectively communicate to beneficiaries considering switching to an MA plan that they may not be able to return to their Medigap policy, thereby significantly limiting their ability to return to traditional Medicare. MA insurers should also be required to communicate this limitation.

Prescription Drug Plan Limits

CMS proposes to codify its existing requirement that PDP sponsors can offer no more than three stand-alone prescription drug plans in a region – one basic plan and no more than two enhanced plans. This requirement minimizes the risk of sponsors using multiple offerings to segregate enrollees into different plans based on risk and to ensure beneficiaries are able to choose from among meaningfully different options.

CMS states that allowing plan sponsors more flexibility to offer options could promote innovation and encourage tailored options targeted to different beneficiary preferences. CMS analyzed Part D plan data and found, however, that markets with a greater number of enhanced plans have higher costs. As a result, it proposes to retain the existing 3-plan limit and states that doing so reflects a balance between limiting but not eliminating the potential risk segmentation and ensuring meaningful choice for enrollees.

CMS seeks stakeholder input on the potential impact of expanding the number of enhanced plan alternatives beyond two. AARP has commented in the past about the importance of preventing confusion by requiring meaningful differences between plan offerings; expressed concerns about adopting policies that would have the result of a proliferation of plan options that do not provide any significant improvement over other plan choices offered to beneficiaries; and discourages

policies that could permit sponsors to use plan options to encourage risk segmentation based on benefit design.

New Special Enrollment Periods (SEPs)

AARP support CMS' proposals to establish two new special enrollment periods to allow enrollees to choose a different plan if the plan they are enrolled in is placed into financial receivership by a state or territorial regulatory authority or if their plan is identified as a low performing plan (plans with summary ratings of fewer than 3 stars for three or more years).

Special enrollment periods enable individuals to maintain coverage in the event of unusual or special circumstances like those described above. They ensure continuity of coverage for enrollees and help to retain a balanced risk profile among individuals. Increasing access to quality, affordable coverage is a general principle that guides our advocacy for older Americans. SEPs are important because they provide consumers with protection from gaps in coverage allowing them to enroll when they experience major life changes that are outside of open enrollment periods. We urge CMS to expand the use of SEPs, particularly given that the importance of accessible and usable SEPs has grown in the current challenging health care pandemic.

Thank you for the opportunity to comment on these important issues. If you have any questions, please do not hesitate to contact me or have your staff contact Brendan Rose on our Government Affairs staff at 202-434-3770 or brose@aarp.org.

Sincerely,



David Certner
Legislative Counsel and Policy Director
Government Affairs