MEDICARE RIGHTS CENTER
266 West 37th Street, 3rd Floor
New York, NY 10018
212.869.3850/Fax: 212.869.3532

April 6, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-4190-P
P.O. Box 8013
Baltimore, MD 21244-8013

VIA ELECTRONIC SUBMISSION

RE: CMS-4190-P: Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

The Medicare Rights Center (Medicare Rights) appreciates the opportunity to comment on the proposed rule **Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly**. 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 three million people with Medicare, family caregivers, and professionals each year.

Medicare Rights generally supports the transition of many of the provisions in this proposed rule from subregulatory guidance to notice-and-comment rulemaking. While we recognize that formal rulemaking can lack the flexibility and nimbleness of guidance, we believe that the standardization, transparency, and predictability of formal rulemaking makes it a more appropriate vehicle for most provisions that make significant changes to the Medicare program.

II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018

A. Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)

Washington, DC Office:
1444 I Street NW, Suite 1105
Washington, DC 20005
202.637.0961

www.medicarerights.org www.medicareinteractive.org

The Centers for Medicare & Medicaid Services (CMS) proposes to require plans to base determinations for eligibility for SSBCI on objective criteria, to document their determinations, and to make those documents available to CMS upon request. We support these proposals. However, CMS does not propose to require Medicare Advantage (MA) plans to submit the process they will use to identify chronically ill enrollees for the purposes of offering SSBCI. We suggest that as plans adopt new SSBCI, they should be required to submit their proposed processes to CMS for clearance before the benefits are instituted, including which social determinants of health they are considering. This would ensure that the processes are sufficient and are not discriminatory or otherwise skewed in inappropriate ways.

CMS proposes to allow MA plans to consider social determinants of health when deciding whether an SSBCI offering is likely to improve or maintain the health of a chronically ill enrollee. We support this codification, with the caveat that such consideration cannot be discriminatory. The social determinants play an outsized role in health outcomes and better addressing need will improve health and well-being for people with Medicare. We note that social determinants are just as important for people in Original Medicare and we urge the agency to consider ways that coverage of services or supports be extended outside of MA.

B. Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§422.101)

CMS proposes to implement §50311 of the Bipartisan Budget Act of 2018, which would increase care management requirements for SNPs, and to apply these changes to all forms of SNPs. We support this implementation and extension to all SNP types.

CMS proposes to require that each MA organization offering a SNP provide those enrollees with access to an interdisciplinary team that includes providers with demonstrated expertise and training. CMS also proposes that plans are in the best position to identify a team that meets these requirements. We are cautiously supportive of this proposal and encourage CMS to engage in rigorous oversight to ensure plans truly are providing appropriate interdisciplinary team access for enrollees.

CMS proposes to require a face-to-face encounter between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff on at least an annual basis, if the beneficiary agrees. We appreciate the acknowledgement that some enrollees may not wish to have a face-to-face encounter and must not be required to do so. We also appreciate the proposal that the encounter may be done via telehealth.

E. Contracting Standards for Dual Eligible Special Needs Plan (D-SNP) Look-Alikes (§ 422.514)

Medicare Rights is encouraged to see CMS taking steps to address this issue. MA plans must be held to a high standard to serve the Medicare population and true D-SNPs can play a valuable role in helping dually eligible individuals access the care they need through enhanced care coordination and integration between Medicare and Medicaid. Look-alike plans are standard MA plans and do not meet the standards of DSPs.[1] The look-alike plans are interfering with efforts to better serve people who are dually eligible for both Medicare and Medicaid by luring dually eligible individuals into these plans

[1] 85 Fed. Reg. 9002, 9018.

without providing enhanced services.[2] These proposals would be important steps toward eliminating a risk to dually eligible individuals.

To combat this problem, CMS proposes to codify previous prohibitions[3] that prevent MA organizations from marketing their plan as if it were a D-SNP; implying that their plan is designed for dually eligible individuals; targeting their marketing efforts exclusively to dually eligible individuals; or claiming a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for that plan is in place. We support the codification of these prohibitions.

Importantly, CMS also proposes not to enter into or renew a contract for a D-SNP look-alike ("look-alikes") in any state where there is a true D-SNP and to establish procedures to transition enrollees from look-alikes to other MA plans. We strongly support these proposals, with the exception of the provision to exempt look-alikes in states without D-SNPs or Medicare-Medicaid Plans (MMPs). Deceptive plan design should not be permitted in any state. Exempting states without currently operating D-SNPs/MMPs would leave room for look-alikes to detract from other efforts to coordinate care for duals, like managed fee-for-service. Look-alikes are fundamentally attempts to deceive people with Medicare and cannot be permitted to continue.

CMS proposes to enforce these contracting rules for plans with 80% or higher dually eligible enrollment. We support the theory behind this approach—i.e., determining a plan's intent to target dually eligible individuals based on its projected or actual enrollment—but we urge CMS to set a lower threshold than 80%. We suggest that 50% is a more appropriate threshold to ensure these deceptive plans do not flourish.

In addition, CMS proposes to transition enrollees of look-alike plans into other MA products by crosswalking them to plans offered by the same organization. CMS notes these individuals would have the opportunity to choose another plan since the crosswalk would be timed to occur during the annual coordinated election period. In order to receive enrollees through this method, MA plans would need to have a combined Part C & D premium of $0 and send an Annual Notice of Change (ANOC) to the crosswalked beneficiary. We support these provisions with some stipulations. The ANOC should include provider network information, including discussion of providers known to not be in the receiving plan's network. This should focus specifically on providers the beneficiary has seen in the past year. Plans must also inform their crosswalked enrollees that they may choose another plan, and provide them with clear, understandable information about how and when to do so.

In cases where a crosswalk is occurring and there is a D-SNP offered by the same MA organization, the default crosswalk should be the D-SNP upon proper notice to the consumer informing them of their other options. Plans should not be able to funnel duals into other MA plans when a more integrated option exists.

We also urge CMS to establish a standard for overlapping networks during the crosswalk to help smooth the transition for beneficiaries. Nothing in the proposal would otherwise require significant overlap of network providers, which means the continuity between plans from the same parent organization is less

[2] 85 Fed. Reg 9002, 9020.
[3] *Id.*

relevant. We encourage setting a requirement at 90% overlap. If 90% provider overlap is not met, we recommend that the dually eligible individual be transitioned to Original Medicare.

In addition, we ask CMS to be mindful of the timing of the crosswalks, especially in states that may already be attempting to transition dually eligible individuals into certain plan types. Multiple transitions may cause disruptions in care and confusion. We urge minimizing the number of transitions a consumer experiences, especially over a short period of time.

III. Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

A. Mandatory Drug Management Programs (DMPs) (§ 423.153)

1. Summary and Background of DMPs

CMS has exempted certain categories of beneficiaries from DMPs, including those being treated for active cancer-related pain; residing in a long-term care facility; or receiving hospice, palliative, or end-of-life care. CMS now proposes to also exempt those with sickle cell disease from DMPs. We strongly support this proposal and other exemptions for individuals with severe pain. Such individuals are at risk of losing access to pain medications with DMPs in effect.

B. Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

CMS proposes to modify the definition of "potential at-risk beneficiary" to include a Part D eligible individual who is identified as having a history of opioid-related overdose or prescription drug events (PDE). While we understand the intent of such a proposal, we cannot support it because of its potential for enormous and destructive unintended consequences. For example, this change could cause individuals not to seek follow up emergency care after they have self-treated with Narcan—or have had Narcan administered by non-medical personnel—because they do not want to be put into the at-risk category. It may also dissuade people from accessing drugs intended to treat substance-use disorder (SUD). If CMS moves forward with this proposal, we urge heightened awareness of these pitfalls, as well as increased monitoring.

CMS proposes to use a 12-month lookback period for a record of opioid-related overdose and a 6-month lookback period for a record of a PDE and identifies past overdose as the most predictive risk factor for another overdose or suicide-related event. We seek clarification as to whether the designation as a potential at-risk beneficiary would be lifted once the enrollee is past the 6- or 12-month period post PDE or overdose. While it is true that a history of overdose is predictive, we do not believe the 6- or 12-month cutoff matches a sharp downturn in the risk.

CMS notes that the proposed 12-month lookback period determination would be based on Medicare FFS claims and MA encounter data. This does not appear to account for people who are new to Medicare who may be younger and transitioning from Medicaid, a Qualified Health Plan, or another commercial plan. Such individuals would be no less at risk than long-term Medicare enrollees. We seek clarification as to how or if these proposals would identify people who were not enrolled in Medicare during the lookback periods.

CMS suggests that providers who are newly aware of a beneficiary's history of overdose should consider prescribing the beneficiary an opioid-reversal agent. We strongly support this suggestion and urge relevant authorities to consider making such prescribing mandatory whenever possible.

D. Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

CMS suggests allowing plan sponsors to disclose opioid risks and alternate coverage information to all Part D enrollees but identifies as a disadvantage the fact that this would be largely over-inclusive, in the sense that a significant number of enrollees would receive information that is not, and may never be, pertinent to them. Despite this concern, we support the outlined education plan. A goal of prevention and public health is to ensure that the information has the best chance of getting to the people who need it. In the case of opioids, this could be anyone. Importantly, the lack of a prescription for opioids does not preclude a beneficiary from having used them, due to prescription sharing or other unauthorized use.[4] With respect to the distribution of this and related information, there could also be heightened focus on those who have greater than 7 days of continued opioid use.

E. Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153)

1. ARBs and MTM

CMS proposes to require Part D sponsors to automatically enroll all at-risk beneficiaries in their MTM programs on an opt-out only basis. We suggest also establishing a path for beneficiaries who may not be classified as "at-risk" to opt in to MTM programs. We have heard from beneficiaries who would benefit from being able to join such programs in order to maintain their recovery or at moments where they feel they are at elevated risk.

CMS suggests that plan sponsors may increase beneficiary engagement by following up with those who do not respond to initial offers (for example, by providing telephonic outreach after mailed outreach). We support this suggestion, especially because beneficiaries may not have a fixed address in order to receive mail, so having several options and attempts to make contact is preferable. However, we urge CMS to clarify what type of outreach is permissible within the current marketing guidelines to ensure adequate beneficiary protections are in place with respect to these communications.

F. Automatic Escalation to External Review under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)

Medicare Rights is pleased to see the automatic escalation of certain DMP appeals to external review. CMS proposes that initial and second notices explain that if on redetermination a plan sponsor affirms its at-risk decision, in whole or in part, the enrollee's case shall be automatically forwarded to the IRE for review and resolution. CMS also proposes to clarify that the requirement that the external reviewer solicit the views of the prescribing physician or other prescriber applies to determinations that are auto-forwarded to the external reviewer. We support these proposals.

V. Enhancements to the Part C and D Programs

B. Out-of-Network Telehealth at Plan Option

[4] *See, e.g.*, Kebede A Beyene, et al., "Prescription Medication Sharing: A Systematic Review of the Literature," Am J Public Health, 104(4): e15–e26 (April 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4025682/.

CMS is considering whether to permit Additional Telehealth Benefits (ATBs) to be provided by non-contracted providers who otherwise satisfy ATB requirements. So long as enrollees are not subject to additional costs, and so long as CMS continues to hold plans accountable for monitoring such providers, we can support this expansion.

E. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

6. Measure Weights (§§ 422.166(e), 423.186(e))

CMS proposes to increase the weights of patient experience/complaints and access measures from 2 to 4. We support this proposal.

F. Permitting a Second, "Preferred", Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

CMS proposes to allow Part D sponsors to establish up to two specialty tiers and design an exceptions process that exempts Part D drugs on these tiers from tiering exceptions to non-specialty tiers. We oppose this proposal. While we understand and appreciate the goal is to lower drug costs, tweaking formulary tiering and design is unlikely to have a significant effect on pricing. But it is likely to increase beneficiary confusion. We regularly receive calls from beneficiaries who are struggling to understand their Part D plan formularies or cannot afford their specialty tier medications and are unable to get a tiering exception. Adding another specialty tier simply adds complexity to an already overly-complex system, and exempting specialty tiers from tiering exceptions merely traps beneficiaries with unaffordable drugs. If CMS decides to move ahead with this proposal, we urge either a limited demonstration or, if nationwide, rigorous assessment of its effectiveness through actual lowered prices.

CMS seeks comment on whether a coinsurance higher than 25% to 33% should be permissible for the specialty tier. As we state above, in our experience, people with Medicare already cannot afford medications on the specialty tier. Any increase in costs would only exacerbate these challenges and worsen their lack of access to needed drugs.

CMS also proposes to raise the dollar threshold for a drug to qualify for the specialty tier from $670 to $780 for 2021. We support this increase. The current pricing structure allows far too many drugs onto the specialty tier, negatively impacting beneficiary access and affordability.

G. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

CMS proposes to require Part D sponsors to implement a beneficiary RTBT to allow them to view accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information, including utilization management requirements. As with the prescriber RTBT, Medicare Rights applauds efforts to increase understanding of prescription drug costs to better help people with Medicare afford their therapies. We encourage CMS to work with diverse stakeholders to ensure this RTBT is usable and accurate, and to create and distribute informational resources to help beneficiaries understand how to use the tool. Further, we urge CMS to provide adequate materials and training on the new tool for others who may encounter it, including prescribers, pharmacists, and enrollment counselors.

We also caution against any idea that such tools can or should take the place of robust work to keep beneficiary drug prices down. Having additional shopping tools should not put beneficiaries on the hook for programmatic savings.

CMS also proposes that plans must make this information available to enrollees via their customer service call center. We support this additional requirement to better serve people with Medicare who do not have computer or smart phone access, or who are more comfortable with phone interactions.

CMS flags the need for plans to be mindful of and comply with their current non-discrimination responsibilities and obligations, particularly with respect to individuals who are deaf, hard of hearing, or blind, or who have other sensory or manual impairments. CMS also notes that all data the plans provide must be patient-specific, clinically appropriate, timely, and accurate, and devoid of commercial purposes that would adversely impact the intended functionality of promoting cost-effective beneficiary and prescriber selections of drugs. We appreciate this language and applaud CMS for making plan obligations clear.

We also appreciate the thoughtful discussion of the needs people with Medicare have for complete and accurate information that is curated to avoid encouraging the prescribing of clinically inappropriate medications. We agree that omitting such medications could be appropriate under limited circumstances. However, it might be more effective to list all medications and flag those that are inappropriate as being unavailable under the given circumstances.

H. Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)

CMS proposes to require Part D sponsors to disclose to CMS the measures they use to evaluate pharmacy performance, as established in their network pharmacy agreement. In part because pharmacy performance measures can affect beneficiary cost sharing, we support this requirement. Disclosing this information could also increase transparency and lead to the creation of high-quality performance measures.

J. Dismissal and Withdrawal of Medicare Part C Organization Determination and Reconsideration and Part D Coverage Determination and Redetermination Requests (§§ 422.568, 422.570, 422.582, 422.584, 422.590, 422.592, 422.631, 422.633, 423.568, 423.570, 423.582, 423.584, and 423.600)

CMS proposes to codify the right of enrollees and other parties to request an independent review when a plan dismisses a redetermination request. In addition, the agency proposes to state that if the independent entity determines that the Part D plan sponsor's dismissal was in error, the independent entity would reverse the dismissal and remand the case to the plan for a redetermination on the merits of the case. We support these additions.

VI. Codifying Existing Part C and D Program Policy

E. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

CMS proposes to give MA plans a bonus in-network adequacy credit for contracting with certain specialty providers for telehealth services. We do not support this proposal. Telehealth services should supplement and not supplant beneficiary access to in-person services. We strongly oppose using telehealth as an excuse to reduce plan compliance with network adequacy requirements.

G. Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V)

CMS proposes three new requirements designed to assure that rewards and incentives programs are not discriminatory: 1. Programs must be uniformly offered to any qualifying individual; 2. MA

organizations must provide accommodations to qualifying individuals who would otherwise be eligible for the reward but are unable to perform the target activity; and 3. MA organizations must not tie or limit the availability of the reward to the achievement of a health status measurement. We support these anti-discrimination provisions as a way to prevent rewards and incentives programs from creating significant discrepancies between beneficiaries.

CMS proposes to codify that MA organizations must comply with all communications and marketing requirements when offering a rewards and incentives program. We support this requirement.

CMS solicits comment on whether MA organizations should be required to report specific information to CMS about rewards and incentives programs to support program monitoring and oversight. We support a reporting requirement to ensure that plans are implementing any reward programs fairly and without discrimination.

CMS proposes to codify that a rewards program is not a benefit and must be included as an administrative cost and non-benefit expense in bids. We support this codification.

H. Requirements for Medicare Communications and Marketing (§§ 422.2260 – 422.2274; 423.2260 – 423.2274)

CMS notes that the NPRM is codifying long-standing subregulatory guidance.[5] However, the most recent Medicare Communications and Marketing Guidance (MCMG) made unexpected policy changes that were not included in any previous guidance and are not addressed here.[6] For example, the guidance for the 2020 plan year blurs the line between marketing and education and removes non-English translation disclaimers. The guidance also lacks information regarding supplemental benefits. We ask that these and other provisions be addressed—in the final regulations or additional notice-and-comment rulemaking—as previously outlined.[7]

We also urge CMS to remind plans about their obligations to comply with Section 1557 notice requirements, including "taglines" or disclaimers in the top 15 languages and to conduct enforcement and oversight when appropriate. There is a growing need for stronger translation requirements. We echo our colleagues at Justice in Aging and urge CMS to take this opportunity to revisit 42 C.F.R. 422.2268(a)(7) and require using a threshold of 5% or 1,000 people in the service area, whichever is lower, of a population speaking a language other than English to trigger translations for vital documents.

We appreciate that CMS notes the summary of benefits must include Medicaid benefits for D-SNPs. We also welcome the agency's reiteration that MA plans are prohibited from marketing non-D-SNPs as if they were designed for dually eligible individuals or claiming that they have a relationship with the state Medicaid agency. But more action is needed to protect dually eligible individuals from nefarious marketing.

Specifically, there must be clear guidelines to protect dual eligible enrollees in instances when an agent/broker is disenrolling them out of an integrated product (D-SNP or MMP) and into another plan.

---

[5] 85 Fed. Reg. 9002, 9108.
[6] Medicare Rights Center, Center for Medicare Advocacy, & Justice in Aging, "Medicare Plan Finder and Medicare Communications and Marketing Guidance Letter" (August 27, 2019), https://www.medicarerights.org/pdf/082719-mpf-mcmg-2020-letter-cms.pdf.
[7] *Id.*

The agent/broker must be required to accurately and clearly explain to the individual what they are disenrolling from and into—including what a non-integrated product means for their care. The same requirements should exist for the outbound enrollment verification call, and CMS should require actual contact with the consumer during the call. We also urge prohibition of D-SNP marketing except to those enrolled in an affiliated Medicaid plan.

J. Prescription Drug Plan Limits (§ 423.265)

CMS proposes to limit Part D sponsors to no more than three plans per region. We support this limitation. In our experience, a proliferation of plans merely adds confusion for beneficiaries who already struggle to cope with the multiplicity of plan options.[8] And this effect may be even more pronounced when differences between plans are small or subtle.

L. Call Center Requirements (§§ 422.111 and 423.128)

CMS proposes to require that interpreters be available within 8 minutes of reaching the customer service representative and that the interpreter be available at no cost to the caller. The agency also proposes explicitly requiring call centers to respond to TTY-to-TTY, consistent with standards under existing law. We support these requirements.

M. Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)

As we stated in our opening remarks, Medicare Rights supports the transition from subregulatory guidance to notice-and-comment rulemaking in most circumstances. The codification of the outlined SEPs ensures that this information is more transparent and provides greater stability for beneficiaries. We also appreciate that the list is explicitly not exhaustive and that CMS retains the ability to create new SEPs for circumstances as they arise.

VII. Proposed Changes to the Programs of All-Inclusive Care for the Elderly (PACE)

A. Service Delivery Request Processes under PACE (§§ 460.104 and 460.121)

CMS solicits comments on a proposal to expand the scope of individuals who can make a service delivery request to the PACE interdisciplinary team (IDT) on behalf of a PACE participant to include caregivers, providers, or prescribers. We support the ability of each of these categories of individuals to make a service delivery request on behalf of a PACE participant. This approach could increase the involvement of caregivers and distribute the burden of transmitting provider or prescriber recommendations to the IDT.

CMS also proposes that service delivery requests may be made either orally or in writing and may be made to any individual who provides direct care to a PACE participant. We support this proposal and urge the requirement of thorough record-keeping so that all requests are recorded and verifiable, including who is making the request and their authority to do so. Oral requests are easy and non-burdensome and PACE participants may be confused about the roles or authority of various employees or contractors. This proposal would allow the greatest access to service delivery requests for the participant.

[8] Phil Galewitz, "Do Seniors Have Too Many Medicare Plans to Choose From?" Kaiser Health News (May 14, 2014), https://khn.org/news/do-seniors-have-too-many-medicare-plans-to-choose-from/.

CMS proposes that all service delivery requests must be brought to the IDT as expeditiously as the participant's condition requires, but no later than 3 calendar days after the date the request was made. We support this timeline, with the caveat that the determination of what the participant's condition requires should be strongly biased toward assuming the participant's condition requires immediate action. We also support the proposed timeline that would require the IDT to respond within 3 days of receiving the request, or faster if the participant's condition requires as well as the requirement that any extensions be documented to demonstrate why the extension is in the interest of the participant.

In addition, CMS proposes that if a member of the IDT receives a service delivery request and is able to approve the request in full at the time the request is made, the PACE organization would not be required to follow certain processing requirements. This would not apply if the member cannot approve exactly what is requested. And the member would still be obligated to record the request and decision. We support this flexibility, as long as proper documentation is still required.

CMS also proposes that the IDT must consider all relevant information when evaluating a service delivery request, including the findings and results of any reassessment(s) conducted in response. For example, the agency notes that it would be inappropriate for the IDT to make a decision based on the participant's physical needs without considering their emotional and social needs in a case where they are seeking additional emotional and social supports. In such cases, the emotional and social needs are the most relevant information. We support this requirement.

CMS proposes that only a denial or partial denial of a service delivery request would trigger the need for a reassessment. We support this proposal.

The agency also proposes that any denial or partial denial must be accompanied by notice, both orally and in writing, delivered to the participant or their designated representative. All such notices must state the specific reasons for the denial, including an explanation of why the service is not necessary to improve or maintain the participant's overall health status and be specific to the participant, taking the participant's medical, physical, emotional, and social needs into account. It would include the results of any reassessment(s) conducted by the PACE organization and it would have to be stated in understandable language so that the participant or designated representative can comprehend why the request was denied. We support these proposals. We encourage CMS to provide some template language to help PACE organizations phrase complex decisions in understandable ways. In instances where the service request is made on behalf of the PACE participant, we urge they nevertheless be provided a copy of or access to the written notice.

CMS also proposes to require the PACE organization to automatically process a participant's request as an appeal when the IDT fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care. We support this proposal. This would prevent participants or caregivers from having to closely monitor requests and ensures access to the appeals process.

CMS proposes PACE organizations must establish and implement a process to document, track, and maintain records related to all processing requirements for service delivery requests, and that PACE organizations must account for, and document, requests received both orally and in writing. As noted above, we support these requirements, including for service delivery requests that were approved in full at the time the request is made.

B. Appeals Requirements under PACE (§§ 460.122 and 460.124)

CMS proposes codifying that a participant's designated representative has the right to appeal on the participant's behalf. Additionally, CMS proposes that PACE organizations must include procedures for receiving oral and written appeal requests. We support these proposals.

CMS also proposes that PACE organizations must ensure appeals are reviewed by an appropriate reviewer or committee that is be both independent and appropriately credentialed, and that the credential be in a field or discipline related to the appeal. CMS also proposes to require that PACE organizations ensure their reviewers understand the PACE program as well as how to review requests, and that the organizations provide reviewers with written or electronic materials explaining that services must be provided consisted with PACE requirements. We support these proposals.

CMS proposes that if appeal decisions are favorable to the participant, the PACE organization would be required to explain any conditions on the approval in understandable language. For adverse decisions, the organization would be required to state the specific reason(s) for the denial, explain the reason(s) why the service would not improve or maintain the participant's overall health status, inform the participant of his or her right to appeal the decision, and describe additional appeal rights. We support these requirements and urge mandating their timely delivery.

CMS clarifies that a participant always maintains the right to file a service request without assistance from the PACE organization and may choose to pursue and appeal through either the Medicare or Medicaid processes. We support these clarifications.

C. Access to Data and Safeguarding Records under PACE (§ 460.200)

CMS proposes to require PACE organizations to maintain all written communications received from a participant or other party on their behalf in their original form when the communication relates to the participant's care, health, or safety. We agree with this proposal.

D. PACE Services, Excluded PACE Services, and the Interdisciplinary Team (§§ 460.92, 460.96, and 460.102)

3. Responsibilities of the Interdisciplinary Team

CMS proposes to require the IDT to remain alert to pertinent input about participant needs from employees, contractors, and specialists and to document all recommendations for care and services and, if not approved, the reasons for not approving. We support these proposals.

E. Documenting and Tracking the Provision of Services under PACE (§ 460.98)

CMS proposes to retain the requirement that PACE organizations establish and implement a written plan to furnish care. The agency also seeks to add a requirement that the plan ensure that care is appropriately furnished. Additionally, CMS clarifies that the PACE organization is responsible for providing this care regardless of the care setting. We appreciate and support these modifications and clarifications.

CMS further proposes to require that all services be provided as expeditiously as the participant's health condition requires, taking into account the participant's overall medical, physical, emotional, and social needs. And the agency also proposes to require PACE organizations to document, track, and monitor the

provision of services across all care settings, regardless of whether services are formally incorporated into the participant's plan of care. We support these requirements.

F. Documentation in Medical Records under PACE (§ 460.210)

CMS proposes to require the PACE organization to document all recommendations for services made by employees and contractors of the PACE organization, including by all specialists such as dentists, neurologists, cardiologists, and others, in the participant's medical record. Also, CMS proposes to require the IDT to document in the medical record the reason(s) for not approving or providing a service recommended by one of these sources. We support these proposals.

CMS also proposes to require PACE organizations to maintain certain written communications received by the PACE organization in the participant's medical record, including communications from the participant, his or her designated representative, family members, caregivers, or any other individual who provides information pertinent to a participant's care, health, or safety, as well as communications from advocacy or governmental agencies like an Area Agency on Aging or Adult Protective Services. We support this proposal.

G. PACE Participant Rights: Contact Information and Access Requirements (§ 460.112)

CMS proposes to add three new participant rights to increase beneficiary protections: 1. The right to contact 1-800-MEDICARE for information or to make a complaint; 2. The right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines; and 3. The right to receive necessary care across all care settings, up to and including placement in a long-term care facility when the PACE organization can no longer maintain the participant safely in the community through the support of PACE services. We support the addition of these rights to the regulations.

Conclusion

Thank you again for this opportunity to comment. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Julie Carter, Senior Federal Policy Associate at JCarter@medicarerights.org or 202-637-0962.

Sincerely,

Fred Riccardi
President
Medicare Rights Center