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Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services, Department of Health and Human Services,
Attention: CMS-1807-P
P.O. Box 8016
Baltimore, MD 21244-8016

September 9, 2024

Re: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments (CMS-1807-P)

Dear Administrator Brooks-LaSure;

The Robert J. Margolis, MD Institute for Health Policy at Duke University (Duke-Margolis Institute) appreciates this opportunity to comment on Calendar Year (CY) 2025 updates to payment policies under the Physician Free Schedule (PFS) and other changes to Part B payment and coverage policies, as well as updates to the Medicare Shared Savings Program (MSSP), henceforth known as the Proposed Rule.

About the Duke-Margolis Institute

Established with a founding gift through the Robert and Lisa Margolis Family Foundation, the Duke-Margolis Institute aims to generate and analyze evidence across health policy and practice to support the triple aim of health care–improving the experience of care, the health of populations, and reducing per capita cost. The Duke-Margolis Institute's activities reflect its broad multidisciplinary capabilities, fueled by Duke University's entrepreneurial culture. It is a university-wide program with staff and offices in both Durham, North Carolina, and Washington, DC, and collaborates with experts on health care policy and practice from across the country and around the world. The mission of the Duke-Margolis Institute is to improve health and the value of health care through practical, innovative, and evidence-based policy solutions. The Institute's work includes identifying effective delivery and payment reform approaches that support the transition to value-based care and collaborating with expert stakeholders to identify pathways to increase the value of biomedical innovation to patients – both through better health outcomes and lower overall health care spending.

As described in some of our recent previous work, including on modernization of risk adjustment and developing longitudinal specialty care payment models, our approach to evidence generation and accelerating the implementation of effective policies at the national, state, and local levels leverage a unique, multistakeholder process, that is also backed by our quantitative expertise in a range of health-

related datasets. Our faculty and staff's experience in analyzing policy and data to develop practical policy solutions and insights into CMS' programs, together with our engagements with diverse stakeholders, have helped guide our responses here.

Introduction

CMS has been at the forefront of improving value in our nation's health system, and many of the most important payment reforms that CMS has scaled across its programs were first tested in PFS, which not only serves as an incubator for great innovations, but also acts as a bellwether for other payers and providers. We commend CMS for its continued commitment to innovation as it seeks to have 100% of Medicare beneficiaries, including those in Medicare Advantage, in accountable relationships by 2030 – though we recognize that progress toward this goal will need to accelerate substantially to meet it. The CY 2025 PFS builds on several of the important innovations, while aiming to maintain a sustainable and predictable payment system. Our comments focus on how to accelerate progress in terms of moving the Medicare system to a more accountable, whole-person delivery and payment system, while addressing key provider concerns, including potential uncertainty about how to respond to changes in fee-for-service (FFS) Traditional Medicare (TM) while navigating participation in Innovation Center (CMMI) models.

As CMS continues to make improvements to its fee schedule, including those outlined in this proposed rule, and release additional opportunities for providers to participate in advanced alternative payment models (AAPMs) through CMMI demonstrations, we encourage the Agency to ensure that additional opportunities in the fee schedule work synergistically to incentivize providers to ultimately move to AAPMs. While the policies in this Proposed Rule do make incremental progress in support of the 2030 goal, they may also inadvertently create opportunities for providers to remain in FFS as opposed to transition them toward more population-based payments. Said differently, additional FFS codes that support the important cognitive, non-visit related activities may continue to bifurcate provider revenue streams without additional steps by CMS to connect these to AAPMs. Our comments across these proposals are connected by a common theme that additional policy actions need to align with the overall AAPM strategy.

Our comments are informed by a range of research at the Duke-Margolis Institute, all of which support acceleration of adoption of equitable, accountable care that supports increased access to comprehensive care and improved outcomes for patients. These include the following examples:

- *Engaging Specialists in Value-Based Payment Models:* In recognition of the increasing role of specialists in managing care across the patient journey, we have released several reports in addition to our above cited specialty vision paper, including a two-part article in *Health Affairs Forefront* that provides strategies to increase specialist engagement in ACO models and value-based payment arrangements. Additionally, we submitted a comment letter on CMS' 2023 Request for Information (RFI) on an Episode-Based Payment Model.
- *Bridging the Home-Based Primary Care Gap in Rural Areas:* To explore opportunities for designing a home-based primary care model that accounts for the unique needs of rural

communities, we conducted qualitative analysis with rural and home-based care experts and synthesized our findings in a *Health Affairs Forefront* article.

- *A Path Forward for Multipayer Alignment to Achieve Comprehensive, Equitable, and Affordable Care:* To identify opportunities to reduce burden from participation and accelerate the adoption of accountable care models, especially more advanced, risk-bearing models, our framework for multipayer alignment provides practical policy recommendations and an implementation path.

- *ACO REACH And Advancing Equity Through Value-Based Payment:* A two-part series in *Health Affairs Forefront* that explores opportunities to address equity through value-based payment model by embedding equity-focused design elements support care for underserved populations.

Below, we provide more specific feedback on the following topics and provisions:

I. Opportunities for a More Unified Strategy to Leverage Innovation Center Models and to Accelerate Accountable Care in CM Programs
II. Telehealth
III. Enhanced Care Management and Request for Information: Advanced Primary Care Hybrid Payment
IV. Digital Therapeutics
V. Opportunities in the Medicare Shared Savings Program to Address Unmet Social Needs and Advance Health Equity
VI. Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care

Opportunities for a More Unified Strategy to Leverage Innovation Center Models and to Accelerate Accountable Care in CM Programs

As part of its accountable care strategy, CMS has committed to increasing the impact of accountable care design elements by y scaling effective CMMI interventions into the Medicare program. We commend CMS' continued efforts to take learnings from CMMI model tests to refine and expand permanent alternative payment models in CM (including past advanced primary care models, ACO models, and the current ACO REACH program that are informing the future of the Medicare Shared Savings Program (MSSP), with the ultimate goal of improving health outcomes for patients. CMS is being intentional about scaling promising practices identified in CMMI models, including advanced primary care model design elements in the proposed advanced primary care management (APCM) codes, as well as the proposed Cardiovascular Risk Assessment and Risk Management codes that were informed by the implementation and learnings from the CMMI Million Hearts model.

We encourage CM and CMMI to build on this approach, not only to incorporate sustainable accountable care design elements into the core chassis of MSSP, but to recognize that MSSP is an increasingly well-established foundation for achieving CMS' goal of widespread availability of longitudinal, coordinated, person-centered care in Medicare – with a needed focus on extending complementary APMs that

engage a boarder set of providers and services. Leveraging MSSP to advance adoption of accountable care arrangements can be achieved through the key principles we outline above, including that policies across both CMMI and CM programs should be well-coordinated to provide clear incentives for all providers to move into accountable care arrangements that build on MSSP. This principle suggests, for example, that any transitional or longer-term reforms in Medicare Incentive Payment System (MIPS) payments should create incentives and supports for moving into accountable care arrangements. In other words, they should be linked to elements or activities that are clearly part of existing or announced APMs, so that it is clear to the providers that MIPS will reduce the costs and increase the ease of succeeding in a permanent Medicare APM.

A related principle is that any new CM payments in TM that facilitate coordinated, longitudinal care are likely to work better – that is, be used in a way that improves outcomes and lowers costs – in an accountable care environment like MSSP, than in uncoordinated FFS that incentivizes volume over value generated from comprehensive care coordination. This principle suggests that providers in accountable care models such as advanced MSSP programs or Transforming Episode Accountability Model (TEAM) pilots, among others, should have more flexible and larger payment opportunities to support team-based care or telehealth – since there are financial incentives (and clear evidence) that such additional payment flexibility is more likely to lead to improved outcomes without overall spending increases when used by providers with significant accountability for outcomes and total cost. A third principle, largely beyond the scope of the current comment opportunity but critical for the future, is to align incentives and supports for APMs across TM and Medicare Advantage.

I. Telehealth

Telehealth is an important modality for increasing access to care and facilitating care continuity across the patient journey. The evidence to date has been mixed, but mostly promising on improving access and maintaining quality. However, there is need for more systematic evidence, including to directly address concerns that expanding telehealth benefits may lead to higher Medicare spending without necessarily enhancing care coordination and outcomes if not integrated into a comprehensive primary care and care coordination strategy. There are multiple provisions in the proposed rule related to the payment for Medicare telehealth services that align with our research around enhancing care access to those who are medically and socially underserved. Notable changes include expanding the definition of telecommunications to include audio-only telehealth visits when a patient does not have access to or does not consent to video telehealth visits, allowing supervisory physicians to provide "direct supervision" through real-time audio and visual interactive telecommunications, and continuing to allow teaching physicians to use telehealth for services furnished involving residents in all teaching settings for virtually furnished services.

As we have previously written, audio-only telehealth visits are an important modality for rural communities, as they accommodate for a lack of broadband connectivity or video conferencing technologies. Expanding the definition of telecommunications to include audio-only telehealth visits may also require developing appropriate use-case examples to ensure adequate safeguards such as requiring

in-person touch points between a certain number of audio-only telehealth visits or defining time-of-response requirements for a provider to reach a rural patient (for example, CMS's Acute Hospital Care at Home waiver requires emergency personnel to be able to reach a patient within 30 minutes).

Our research has also highlighted the role of using telehealth to facilitate direct supervision of physicians, particularly for high-need populations in rural areas who face barriers to accessing care in traditional settings. Stakeholders noted that direct supervision through telehealth was an important tool for ensuring care access and helps address the primary care provider workforce shortage. There is also opportunity to enhance care access through the continuation of the policy permitting teaching physicians to bill for services involving residents with virtual presence at residency training sites located outside of metropolitan statistical areas.

Generally, we acknowledge the need for additional evidence on the safety and appropriateness of services rendered through telehealth services. We offer two considerations as CMS continues to refine its approach for the provision of telehealth services and the use of telecommunications. First, evaluations should consider the impact of the continued temporary extensions for telehealth services on outcomes. For instance, the uncertainty around the future of telehealth flexibilities may have hindered smaller and less-resourced providers' commitment to investing in the necessary infrastructure. Second, while some best practices for telehealth may be challenging to evaluate, they can enhance the care experience. An example of this is utilizing community health workers (CHWs) to facilitate virtual interactions between patients and providers. As CMS works to continue to refines its telehealth policies, we recommend engaging rural providers and providers who have expertise in providing health care services to people outside of traditional clinical settings to share their on-the-ground experience.

To address concerns that telehealth expansions might increase costs without improving outcomes, CMS should introduce a more "advanced" version of telehealth payments for providers who participate in AAPMs, such as MSSP. This approach offers several advantages over the proposed policy of expanding FFS billing pathways. It would allow CMS to expand billing and utilization opportunities in a way that has proven effective with FFS billing, improving outcomes without raising costs, and also incentive overall participation in more advanced accountable care models. CMS can then assess whether telehealth billing patterns in APMs lead to higher spending relative to use of telehealth billing in less coordinated delivery settings, while also helping providers learn to use these services more effectively.

II. Enhanced Care Management and Request for Information: Advanced Primary Care Hybrid Payment

CMS proposes to establish three new codes to better recognize and describe advanced primary care services, encourage primary care practice transformation, and help ensure that patients have access to high quality primary care services—the advanced primary care management (APCM) codes. Recognizing that evaluation and management codes do not fully distinguish and account for the resources associated with primary care and other aspects of longitudinal care, and that other, relatively recent care management codes, such as chronic care management and principle illness navigation, still remain

relatively unbilled, these new G-codes would reimburse providers for *all primary care and services*, and practices would be required to meet the following capabilities:

- 24/7 access to care and care continuity
- Comprehensive care management, including a care management plan
- Management of care transitions
- Practitioner, home-, and community-based care coordination
- Enhanced communication opportunities (e.g., asynchronous communication)
- Patient population-level management (i.e., identifying and filling gaps in care)

Additionally, practices would be assessed based on quality, cost, and data sharing measures. While not all of the above "services" or code elements would need to be billed during the service-month, any "billing practitioners and auxiliary personnel must have the ability to furnish every service element and furnish these elements as is appropriate for any individual patient during any calendar month. Code levels would function similarly to risk-adjusted per-beneficiary/per month (PBPM) payments for care management under CMMI models (support funding for care managers, BH providers, and other staff) on a prospective basis to promote stability and flexibility of use.

An illustrative example of how these codes, if finalized, could support improved care outcomes is related to hepatitis C care. We have identified in previous work opportunities to leverage advanced primary care to support diagnosis and treatment of hepatitis C through the provision of comprehensive care across the continuum of services. Although hepatitis C is curable through direct acting antivirals (DAAs), there are many activities that providers must invest in to connect patients with treatment, including a two-step diagnostic process followed by prescription and adherence to a curative DAA therapy. Patients may face multiple challenges accessing treatment and care, including a lack of provider awareness of prescribing requirements, provider shortages, lack of awareness of testing or treatment sites, or stigma. Coding that supports advanced primary care can help physicians take actions that can support patients throughout the treatment pathway with appropriate reimbursement.

Reimbursement for comprehensive care management and coordination with home and community-based social service providers represented in these new codes would allow for primary care providers to better link care between hepatitis C diagnosis and treatment. For example, many community health centers and other primary care settings require integrated support for prescribing and managing DAA treatments. Practices without this support are more likely to refer patients to specialists. Sending patients to specialists may both increase costs and increase barriers to treatment, as some patients may have limited access to specialty care.

Similarly, CMS also makes a request for information seeking feedback on a variety of questions related to five foundational components on a proposed hybrid payment that builds off of the APCMs:

- streamlined value-based care opportunities
- billing requirements
- person-centered care
- health equity, clinical, and social risk
- quality improvement and accountability

As CMS describes, primary care serves as bedrock for whole-person, accountable care in the US health system. While many accountable care models, such as Comprehensive Primary Care and MSSP, have sought to bolster primary care's net position, primary care remains challenged in care coordination and longitudinal disease management under the current fee schedule reimbursement system. However, as this Proposed Rule notes, The Agency has learned a great deal through these and other models, as well as other innovations it has tested through the fee schedule and proposes to address the issue of lack of incentive to provide population-based non-visit activities under the current system (e.g., care coordination, data-driven quality improvement, and enhanced care management for high-risk beneficiaries).

APCM and similarly enhanced, hybrid payments can provide more stable, predictable payments to support necessary investment in infrastructure and care coordination. Moreover, they can support practices, especially smaller, rural practices in the investment in and utilization of accountable care design elements, i.e., making initial investments across key capabilities. This is particularly true for providers serving high-needs older adults and those with complex health and social needs who struggle to access care in traditional care settings. As we have previously written, many home-based primary care providers are small, independent practices who lack the capital or organizational capacity to take on risk. The proposed codes also represent a step towards paying for primary care services with hybrid payments to support longitudinal relationships between primary care providers and beneficiaries by paying for care in larger units of service, and also help drive accountable care. Physicians and advanced practice providers in Shared Savings Program ACOs, and some CMMI models satisfy requirements for these codes.

Although this is an important step in infrastructure development to support longitudinal, coordinated care, as we note above, it is critical that CMS develop a well-coordinated approach across CMS and CMMI to provide incentives for providers to transition to accountable care arrangements, particularly AAPMs. We encourage CMS to explore opportunities to incentivize providers to leverage new APCM codes while participating in accountable care programs such as MSSP, ACO Primary Care Flex (ACO PC Flex), or Making Care Primary (MCP). For example, CMS could consider implementing the APCM codes with more flexible and less burdensome rules and/or more favorable amounts for providers who are participating in MSSP or other relevant CMMI AAPMs. In particular, CMS should design these payments and provide clear guidance on how providers who participate in models like ACO PC Flex and MCP would have more flexibility and more likelihood of success by participating in a model and utilizing ACPM, versus deciding to invest in one or the other. This would incentivize participation in AAPMs, as well.

In general, moving to a simpler reimbursement system that optimizes clinical flexibility, while improving affordability, equity and quality of care will require a stepwise approach to accelerate participation in AAPMs, like ACO PC Flex or MCP. An important part of this stepwise approach are these types of "hybrid" or "bundled code" structures, where clinicians are able to address a variety of whole-person care needs through codes that aggregate services into a broader person-level payment. These will help incentivize provider participation and help them gain experience in core components of accountable care, while also sustaining providers during model transitions while models are certified, expanded, scaled, improved, etc. However, it will be important for CMS to intentionally invest in incentivizing provider participation in whole-person AAPMs not built on the FFS system in the coming years to reach the 2030 goals.

To that end, our primary feedback on APMCs and the numerous important questions CMS raises is to balance the need for improved population-management and supporting a diversity of practice needs with the burden of a complex payment mechanism that is challenging for providers to bill. Indeed, while ultimately the goal is to provide a meaningful transition path to more advanced accountable care arrangements, the inherit structure of the fee schedule limits this compared to value-based arrangements. For example, while some providers may be willing to take on broader accountability for billing these codes, how quality reporting and risk adjustments are operationalized challenges these new payments. As CMS considers additional opportunities such as this hybrid payment, it needs to clearly articulate how these proposals build toward more encompassing, whole-person models such as those noted above. Each of these specific new FFS billing opportunities is directionally aligned with coordinated, longitudinal care but by themselves do not support the breadth of payment reform needed to succeed and thrive in an accountable care model. Investing in APCM and hybrid payments under a FFS-only infrastructure may lead to additional billing without a clear connection to improved outcomes.

III. Digital Therapeutics

Digital health technologies (DHTs) have emerged as a promising category of health care interventions that leverage technology to prevent, manage, or treat medical conditions. These innovative products have great potential to improve care for patients, both through improved outcomes and by moving care to the home. Over the last few years, the U.S. has witnessed rapid growth in the development, regulation, and adoption of DHTs across different disease areas. In concert, notable progress has been made in payment for some types of DHTs, including remote physiological monitoring (RPM) and some AI-enabled clinical tools.

Despite these advances, significant challenges remain for reimbursement for other categories of DHTs, particularly prescription digital therapeutics (PDTs)—defined as health software that delivers a direct medical intervention to treat or manage a disease, disorder, condition, or injury. One challenge for reimbursement of PDTs is that these tools do not neatly fit into current benefit categories. While PDTs are authorized by the U.S. Food and Drug Administration (FDA) as medical devices, they often mimic treatment that would otherwise be provided through verbal exploration, instruction, and coaching by trained clinicians. They are also prescribed and used at home, generally for a set duration—similar to prescription drugs. PDTs also can be paid for in innovative ways such as subscription services since scaling may lead to lower incremental costs compared to a visit by a health care professional. FFS payment does not align well with this cost model.

In the 2025 proposed physician fee schedule, CMS has proposed to create new codes to pay for a subset of PDTs that it termed “digital mental health treatment (DMHT) devices.” This code is for devices “furnished incident to or integral to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care” where a DMHT device is defined “to refer to software devices cleared by [FDA] that are intended to treat or alleviate a mental health condition…by generating and delivering a mental health treatment intervention that has a demonstrable positive therapeutic impact on a patient’s health.”

We appreciate that CMS is proposing payment in this space, and also that the proposed PFS notes the existence of a nationwide behavioral health workforce shortage in their explanation of this proposal. One of the potential benefits of PDTs is that these tools can supplement an overburdened health care workforce. However, we have concerns that the design of the code for the supply of the DMHT tool and patient education could disincentivize the competition on value – efficiency, user experience, and patient outcomes – that should drive technological and therapeutic improvement. Physician service HCPCS codes are reimbursed at a set amount, albeit adjusted for geographic location and other practice factors. The categorical nature of this code means that any qualified digital intervention, regardless of which mental health disease it treats, would be reimbursed at the same amount. As noted in the proposed change, there is considerable variation in the cost of these products currently – and considerable potential for the cost per unit of service and its effective targeting and outcome impact to change over time. Setting a single (or geographic dependent) payment rate limits the incentives for improving effectiveness of these devices through iterative product improvements. It also may create other market distortions, such as incentivizing products geared towards more simple mental health treatments. Finally, the lack of product specific coding also reduces the ability to efficiently collect real world evidence to better understand their impact on health outcomes in a more heterogenous population. This type of evidence collection would be very helpful to CMS to better understand in which populations these treatments may be more effective and evaluate outcomes over time.

So while we welcome this proposal as a first step in this space, we would encourage CMS to consider payment designs that better encourage competition on value if and when they expand coverage and payment to other types of PDTs and (potentially in collaboration between CM and CMMI) alternative payment models for PDTs that better address the concerns we have raised, and that make it easier for providers in advanced alternative payment arrangements to adopt PDTs and incorporate them in their care models. We noted that the proposed fee schedule states that it "encompasses only part of what may be a spectrum of broadly similar products, most of which might require a new statutory Medicare benefit category." That section then states that the proposal does not extend to tools that have not been authorized by FDA. However, there are multiple PDT devices that have been authorized by FDA for conditions that are not categorized as mental health treatment. It would be helpful to clarify which types of PDT devices would need a new statutory benefit category and which may be eligible for reimbursement under current statute.

We believe there is a unique opportunity at this moment in time for CMS to explore innovative value-based product reimbursement methods for a broader spectrum of PDT tools given that the product space is currently limited and there is an ability to capture information, including outcome data, with the device itself. Establishing a coding system more like how physician-administered drugs are coded would allow PDT products to be differentiated by brand and model and there is already a national unique identifier system for medical devices (UDI) that could be used similarly to the national drug code. However, CMS would not necessarily need to use average sales price (ASP) for reimbursement rate calculations. Instead, CMS could establish demonstration projects through CMMI that would base product reimbursement rates on assessment of value of individual PDTs (potentially building on ideas such as Germany's real-world assessment of value) or outcomes-based pricing. Payment could also be

specifically designed to accommodate, and even incentivize, alternative payment arrangements, between providers and developers for these devices, including subscription-based payments.

Once successful value-based reimbursement arrangements have been developed, they could then be scaled within the PDT product space as more eligible devices are authorized, to other novel technologies that may enter the market, and even to more traditional medical products where current product reimbursement methods may be distorting market incentives.

There is additional opportunity for CMS to explore not only product reimbursement policies, but also transformative care redesign under AAPMs (e.g., longitudinal programs like SSP that work synergistically with these steps) to support the utilization of PDT products. As we highlight throughout our response, CMS should invest additional efforts in accountable care programs that can potentially provide greater opportunity for providers to leverage PDTs in patient care to support improved outcomes and lower costs, as providers in AAPMs are incentivized to not bill excessively for services CM is providing additional access to bill for. We also encourage CMS to explore the opportunity to develop a CMMI pilot that involves an accountable payment arrangement (e.g., per-member per-month payments) for PDTs as an alternative to FFS, as MA plans and Medicaid managed care plans are currently doing.

IV. Opportunities in the Medicare Shared Savings Program to Address Unmet Social Needs and Advance Health Equity

CMS' commitment to provide increased and sustained investments in beneficiary services and care coordination infrastructure and advance health equity through MSSP proposals included in the proposed rule will strengthen Traditional Medicare and its value-based care programs. Previous work by Duke-Margolis has highlighted the opportunities to develop and expand on equity-focused VBP design elements in payment models. Several provisions in the proposed rule align with opportunities of note from this research. These include the availability of up-front payments for infrastructure and care in the form of prepaid shared savings (an HCP-LAN Category 3 approach), as well as the use of a health equity benchmark adjustment (HEBA) to more accurately reflect the cost of caring for underserved populations.

Prepaid Shared Savings Option

As noted above, the PFS and CMMI demonstrations serve as important test beds for CMS to learn from and shift elements into permanent programs, including MSSP, as demonstrated by the scaling of the ACO Investment Model into the program as Advanced Investment Payments (AIP) beginning in 2024. The new prepaid shared savings option would build on the AIP available to new ACOs by providing ongoing upfront payments to existing ACOs to support provision of direct beneficiary services (meals, dental, etc.) that are likely to improve health outcomes. Our research has shown that accountable providers have been reluctant to leverage certain waivers or flexibilities to provide certain services in accountable care programs without confirmation from CMS that it would not violate Medicare compliance requirements. If the prepaid shared savings option is finalized, we encourage CMS to provide in subsequent sub-regulatory guidance additional clarification on permitted uses of the funding for direct beneficiary services, particularly services to address unmet social needs, to support provision and utilization of these services and guide use of high-value services. We also acknowledge CMS' emphasis on the importance of ACO partnerships with community-based organizations (CBOs) to provide services that address unmet

social needs. We encourage CMS to include in any subsequent regulatory guidance clarification on how funding can be used to support partnerships between ACOs and CBOs. For example, it would be helpful to clarify if funding could be used to support CBO infrastructure needed to partner with MSSP participants to provide these services, as has been recommended by the Health Care Payment Learning and Action Network's Health Equity Advisory Team in its guidance to support partnerships with CBOs to address HRSNs.

Health Equity Benchmark Adjustment

We support CMS' continued focus on advancing health equity as a key feature of its accountable care strategy, a critical component of which has been the testing of a HEBA through payment adjustments across CMMI models. The proposal to introduce a HEBA in MSSP to account for the true cost of care for beneficiaries enrolled in Medicare Part D low-income subsidy (LIS) or are dually eligible for Medicare and Medicaid in payment adjustments and promote equity by advancing access to care for underserved or vulnerable populations is an important step in reflecting total resource use by patients. CMS is currently testing and refining the implementation of a HEBA in the ACO REACH model, which weighs a beneficiary's Area Deprivation Index (ADI) score with dual-eligible and/or low-income subsidy status. We appreciate CMS' commitment to taking learnings from the testing of ADI use in the ACO REACH HEBA calculation to inform future rulemaking, as it has been noted by experts there are potential limitations of ADI's ability to accurately reflect the high cost of living in urban areas. As CMS continues its efforts to identify the optimal payment adjustment method to ensure health equity is accounted for in VBP arrangements, we encourage CMS to take learnings from models currently testing a HEBA.

CMS should continue to monitor and refine the use of ADI in calculating the HEBA as they learn more from ACO REACH participant experiences, test other payment adjustments to advance health equity, and gather additional information on introducing a HEBA into MSSP from this proposal to most accurately account for the needs of the population. Additionally, we acknowledge throughout our comments the potential for various proposals, including those related to telehealth and digital health, to support care for populations that have often face health disparities. However, there is clear evidence that without explicit policy supports and accountability for addressing disparities, the growing use of new technologies could exacerbate disparities, including the potential for creating new biases in care pathways. As emphasized in our previous work and throughout our response, an opportunity to avoid an exacerbation of existing disparities is to provide a clearer pathway to utilize these additional services in the context of accountable care models, particularly models that take steps to reduce disparities and account for biases in the application of design elements, such as the use of a HEBA in ACO REACH.

V. Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care

We appreciate CMS' commitment to advancing value-based specialty care and agree that perhaps the greatest opportunity for engaging specialists in accountable care is through more longitudinal models that focus on chronic disease management and improved prevention in ambulatory care. As we have previously written, Medicare payment reforms for specialists to date have largely focused on episode-

based payments for major acute events and procedures, which is an important and costly part of health care, but reflective of only one component of how specialty care providers can better support patients' care journeys and health outcomes. Developing new accountable care mechanisms that better integrate specialists across the entire care continuum alongside primary care teams can build on the important successes accomplished to date, that have primarily been related to primary care.

The model proposed in this RFI would allow for some steps forward, including improving data collection for certain types of specialty care, but is insufficient on its own for increasing primary-specialty care integration and advancing comprehensive longitudinal care. We encourage CMS to prioritize pairing this model with a more detailed vision and clearer pathway to link any new MVP steps directly into the features and infrastructure for APMs for longitudinal specialty care. Doing so would complement CMS' ongoing efforts and strategies to improve specialty care, such as the TEAM model, to make more comprehensive progress towards its 2030 accountable care goals.

Major challenges with the proposed model stem from longstanding challenges with the MIPS and Quality Payment Program (QPP) programs more broadly, including the following:

- *Limitations of MIPS to accurately and reliably assess quality:* For the most part, measure options within MVPs do not provide information that is granular enough to show specialists' contributions to care and outcomes beyond acute processes and procedures. Further, we have heard concerns about the ability of MIPS to accurately measure quality and improvements to patient outcomes, as well as generate meaningful distinctions and support comparisons across different types of specialty care practices. Evidence suggests that MIPS may not accurately capture physician performance and care quality, especially for providers caring for more medically complex and socially vulnerable patients and providers without health system affiliations.
- *Administrative burden:* MIPS can be costly and administratively burdensome to report, which can outweigh incentives and supports to participate. Participation may be challenged because the way in which specialty care providers affiliate with (and therefore report through and collect data from) other practices and health systems adds complexity.
- *Misaligned incentives in QPP:* Currently, the MIPS maximum payment adjustment is larger than the AAPM bonus, which disincentivizes shifts to accountable care and participation in AAPMs.
- *Two-year reconciliation:* This model will continue to rely on a two-year reconciliation period for payment adjustments, which has been challenging for motivating meaningful, timely care delivery and quality improvements.

CMS should use this proposed MVP approach to improve the availability and sharing of relevant, reliable, and meaningful measures and data for major specialty-related conditions to provide an initial infrastructure for longitudinal specialty AAPMs. These data should be shared with both primary and specialty care providers to inform quality improvement initiatives and facilitate building accountable care relationships. CMS should do this by:

- Continuing to prioritize the collection and expanded role of meaningful, high-quality patient-reported outcome-based performance measures (PRO-PMs), patient-reported experience

measures, and functional status measures across MVPs, along with the necessary supporting infrastructure, consistent with the CMS National Quality Strategy. CMS' inclusion of measures related to functional status in several MVPs, as well as CMS' actions to require the reporting of functional status measures for elective total hip arthroplasty (THA) and total knee arthroplasty (TKA) as part of the Inpatient Quality Reporting program, represent promising first steps in this area. Tracking functional status over longer periods of time could inform high-value care decisions, such as assessing the appropriateness of a surgery or other intervention, or tracking complications or improvements over time. CMS could build on existing, validated functional status and patient-reported outcome measures and instruments across specialties, including PROMIS.

- Developing and reporting more longitudinal cost measures. Most cost measures within MVPs are limited to episode-based cost measures, which do not provide insight into where and how specialty care providers are contributing to improvements in longitudinal patient outcomes and lower spending outside of episodes. CMS could implement a pay-for-reporting program for such measures in MIPS/MVPs, with a pathway to reimbursement as part of longitudinal specialty models across multiple conditions.
- Building on the provision of "shadow bundle" data to ACOs and the inclusion of specialty care metrics in MCP's data feedback tool to better promote primary-specialty care collaboration on high-value, longitudinal care delivery. Some health plans in Medicare Advantage and commercial markets are using similar approaches to help inform and support value-based specialty care partnerships. This should work synergistically with CMS' efforts to improve Medicare Advantage data, as we described in our response to the recent RFI.

As noted above, CMS should develop a roadmap from MIPS/MVP payment adjustments to a specialty ambulatory/longitudinal care AAPM, and socialize that transition pathway as part of another RFI to inform model development. In the short term, CMS should prioritize retaining a meaningful AAPM bonus to encourage the shift to accountable care. Next steps could include some form of non-fee-for-service payment to specialists that are "aligned" with accountable primary care groups and a gradual transition to a more advanced APM (e.g., partial or full risk adjusted capitation) that is integrated with or nested within ACO models. This approach would help promote alignment with ongoing VBP models and ACO priorities as well as reduce provider burden associated with participating in multiple models. Our 2022 vision paper and additional research describe examples and pathways for how longitudinal payment models could be developed to augment short-term episode payments and reforms for accountability for longitudinal care. Initial efforts could focus on care coordination payments and support for e-consults for specialty care providers that partner with primary care teams, in alignment with the Making Care Primary model. In the longer term, alternative payments linked to condition management, combined with management of acute event and procedure episodes within conditions, would support not only efficient care within short-term episodes, but also preventive and coordination services designed to avoid costly complications. Such payment models could be phased in over time and could include flexibility in the amount and financial risk involved to facilitate different primary and specialty care arrangements.

Conclusion

We appreciate CMS' commitment to increasing participation in VBP payment arrangements to reach its 2030 accountable care goals through these proposals to strengthen access to comprehensive, equitable whole-person care in the Medicare program. If you have questions or require additional information, please reach out to Rachel Bonesteel, Rachel.bonesteel@duke.edu.

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