September 13, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1734–P
P.O. Box 8016
Baltimore, MD 21244–8016

Dear Administrator Brooks-LaSure,

The Primary Care Collaborative (PCC), a multi-stakeholder coalition of 60+ organizational members ranging from clinicians and patient advocates to employer groups and health plans, appreciates this opportunity to comment on the proposed Medicare Physician Fee Schedule (MPFS) for calendar year 2022.

Primary care is foundational for population health and thriving communities.1,2,3 As a coalition of diverse members, we collectively recognize the urgency - for Medicare, its beneficiaries, and the country—of building an equitable health care system with primary care at its base: care that emphasizes comprehensiveness, longitudinal relationships, and “upstream” determinants for better patient experience and better health outcomes. (See the Shared Principles of Primary Care.) Nowhere is this more important than in communities confronting persistent health inequities.

Unfortunately, pandemic-related disruptions, combined with years of underfunding, have weakened that primary care foundation - weakening it most in communities already weathering systematic racism and generations-long under- and dis-investment. Health centers, a backbone

References:

of the primary care safety net, which served roughly 28 million patients in 2020, (of which 90% are low income and 63% are racial/ethnic minorities) faced more than 1948 temporary closures as of May 2020 and reported a 43% drop in patient visits overall, limiting access to essential primary care service for disadvantaged populations. According to a Larry A. Green Center/PCC Quick COVID-19 Primary Care Survey, fielded between September 18-21, 2020, 54% of primary care practices experienced pandemic-related furloughs and layoffs, and over a quarter of practices reported a significant amount of work that went unpaid and permanent reductions in office staff. One study projected $15.1 billion in losses to primary care in 2020 alone.

To assure equitable access to primary care for every community, it is vital to implement the payment and investment recommendations detailed in the 2021 National Academies of Science, Engineering and Medicine (NASEM) report, Implementing High-Quality Care: Rebuilding the Foundation of Health Care. PCC calls on CMS to make the NASEM report’s primary care payment and investment recommendations central to its equity and value strategy, while maximizing alignment of Medicare payment policy with Medicaid, commercial plans, and other payers.

There must be both higher payments and greater investment in primary care, which in the US is approximately 5-7% of total cost of care and trending down. Primary care practices need pathways to rapidly transition from a predominantly fee-for-service model to predominantly population-based prospective payment (hybrid) models that would include adjustment for health status, risk, social drivers, and other elements. Such hybrid models should be implemented widely, while being mindful of practice heterogeneity, and the need to support greater adoption of telehealth.

For the time being, however, the Medicare Physician Fee Schedule and associated Part B policies continue to structure today’s primary care delivery system – impacting enrollees in traditional Medicare, Medicare Advantage, and all other sources of health coverage. For this reason, PCC commends CMS’ implementation of the Evaluation and Management (E/M) payment increase

on January 1st, 2021, as well as its continuing efforts to sustain practice and telehealth flexibilities established during the Public Health Emergency (PHE). In the CY 2022 proposed rule, CMS offers several positive, if mostly incremental, improvements that build on that important work. PCC supports:

- **Updating the labor component of Practice Expense Relative Value Units (RVUs) using the latest Bureau of Labor and Statistics data in CY 2022.** Over the two decades since the last update, the costs of fielding robust primary care teams have increasingly exceeded actual Medicare reimbursement. Any delay of the update’s implementation would compound this under-resourcing of primary care.

- **Revising and increasing the payment for Part B Chronic Care Management and Principal Care Management Codes.** The proposed revisions represent a much needed, if modest, step toward addressing the undervaluation of care management under the physician fee schedule.

- **Expanding access to medical nutrition therapy (MNT) for individuals with diabetes and kidney disease, by changing the treating physician requirements and updating the chronic renal insufficiency GFR criteria.** Broader access to MNT will support efforts by beneficiaries and their care team to manage these serious chronic illnesses.

- **Allowing rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs) to bill for Transitional Care Management (TCM) and other care management services furnished for the same beneficiary on the same day.** Permitting RHCs and FQHCs to bill for TCM and other care management services will facilitate utilization of high-value care management services, which can decrease avoidable admissions, help address social determinants of health and mitigate health disparities.  

- **Permanently removing the geographic and home-based restrictions on payment for tele-mental health services, as required under the Consolidated Appropriations Act of 2021.** The permanent expansion of tele-mental health services will improve access to mental and behavioral health care for beneficiaries, many of whom may struggle to access these services easily in their own community.

- **Allowing clinicians to provide Opioid Use Disorder (OUD) therapy and counseling services using audio-only technology, when/if two-way video is not available to the beneficiary.** Access to audio-only OUD treatment services has been shown to improve equity and reduce barriers to care.  

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We provide more detailed comments below regarding other specific issues raised in the Notice of Proposed Rule-Making (NPRM):

1. Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis
2. Tele-mental Health Services – Requirement of and Timing for In-person Office Visits
3. Tele-mental Health Services – Requirement of and Timing for In-person Visits (FQHCs/RHCs)
4. Tele-mental Health Services – Coverage of Audio-only Services
5. Diabetes Prevention Program Expanded Model
6. Medicare Shared Savings Program – Addressing the Rural Glitch
7. RFI on Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs
8. RFI on Closing the Equity Gap on CMS Clinician Quality Programs and
9. RFI on Vaccine Administration Services

Note: the number assigned to these comments is for ease of reading and navigation. It does not connote the relative importance of the issues addressed.

1. **Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis (Section# II.D.1c)**

*Description of CMS Proposal or Request for Comment:*
CMS proposes retaining all services previously added to the Medicare telehealth services list on a Category 3 (temporary) basis until the end of calendar year 2023 to consider whether the services should be permanently added to the telehealth list following the COVID-19 PHE.

*PCC Comment:*
PCC supports the proposal to retain services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023. We agree this extension will allow more time for CMS and stakeholders to collect information regarding utilization of these services during the pandemic and collate evidence and other supporting documentation needed to consider permanent addition to the Medicare telehealth services list.

We further recommend CMS add the telephone E/M codes (CPT 99441-99443) to the Medicare telehealth services list on a Category 3 basis. Abruptly ending payment for audio-only telephone services at the end of the PHE will exacerbate access disparities for Medicare beneficiaries without smartphones and poor broadband connectivity. This additional extension will provide more time to collect data and evidence on the importance and quality of audio-only telehealth visits after the end of the PHE.

2. **Tele-mental Health Services – Requirement of and Timing for In-Person Office Visits (Section# II.D.1d)**
Description of CMS Proposal or Request for Comment:
CMS proposes to require an in-person, non-telehealth service be provided by the physician or practitioner furnishing mental health telehealth services within the six months prior to the initial telehealth service—as required by the Consolidated Appropriations Act (CAA). CMS also proposes requiring an in-person visit at least once every six months thereafter.

CMS requests feedback whether the required in-person, non-telehealth service that must occur within six months of a behavioral/mental health telehealth service could be furnished by another health professional within the same group as the one who furnished the telehealth service.

PCC Comment:
Telehealth technologies can increase access to care, improve health outcomes by enabling timely care interventions\(^\text{11}\) and decrease costs when utilized as a component of, and coordinated with, longitudinal primary care.\(^\text{12}\)

As CMS seeks to implement the tele-mental health provisions of the CAA, it should consider the recent dramatic increase of mental health burdens on Medicare beneficiaries. In 2020, the prevalence of serious psychological distress among adults older than 55 reached a level nearly twice that observed pre-pandemic.\(^\text{13}\)

Upon conclusion of the PHE, the proposed rule would apparently bar reimbursement for tele-mental health care, absent an in-person visit in the prior six months. PCC is alarmed by the disruptive impact this could have on beneficiaries' ongoing, longitudinal primary care and behavioral health care relationships. Many of these relationships were established during the lengthy emergency and may involve members of the care team not physically accessible for an in-person office visit. CMS must consider all steps within its authority to delay or avoid such a disruption of the continuity of care.

PCC also opposes the proposed requirement of in-person visits every six months following an initial tele-mental health service and urges CMS to leave the decision about when to engage in

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these in-person visits subsequent to the telehealth visit to the discretion of the patient and their care team.

The distribution of mental health professionals is currently not sufficient to allow in-person access to behavioral health care, particularly among rural communities and communities of color.\textsuperscript{14} During the pandemic, primary care teams in these communities have been able to leverage remote tele-mental health to care for and manage the health of their patients - where few or none may have been previously available. Given the endemic rates of and disparities in mental health disorders predating the Public Health Emergency and increased prevalence during that emergency, additional barriers to comprehensive, whole-person primary care could undermine the agency’s stated health equity goals.\textsuperscript{15,16}

In the event CMS does implement any in-person visit requirement, CMS should permit these visits to be furnished by another health professional within the same group as the clinician who furnished the telehealth service. CMS should not unnecessarily restrict it to health professionals of the same specialty within a group. Any requirement of specialty would restrict groups from determining the most effective and efficient ways for their health professionals to provide care collaboratively and meet patient needs.

3. Tele-mental Health Services – Requirement of and timing for in-person visits (FQHCs/RHCs) (Section # III.A)

\textit{Description of CMS Proposal or Request for Comment:}
As required by the Consolidated Appropriations Act, CMS proposes to require an in-person, non-telehealth service be provided by the physician or practitioner furnishing mental health telehealth services within six months prior to the initial telehealth service. However, CMS also proposes requiring an in-person visit at least once every six months thereafter.

\textit{PCC Comment:}
PCC opposes the proposed requirement of in person visits every six months following an initial tele-mental health service and urges CMS to leave the decision about when to engage in an in-person visit to the discretion of the patient and their care team. Telehealth technologies can

increase access to care, improve health outcomes by enabling timely care interventions and
decrease costs when utilized as a component of, and coordinated with, longitudinal primary
care. As an important source of this kind of care, RHCs and FQHCs should have every
opportunity to deliver telehealth modalities.17 Given shortages of specialty mental health
clinicians particularly in the rural locales, health professional shortage areas and medically
underserved areas, tele-mental health care is particularly important to the delivery if
comprehensive, whole-person primary care for the vulnerable populations served by health
centers.

Therefore, PCC is concerned that CMS has proposed additional requirements for face-to-face
visits in the RHC and FQHC setting. As with CMS’s similar approach to office visit tele-mental
health, we believe additional requirements undercut CMS’ equity goals. We encourage CMS not
to finalize these requirements.

4. Tele-mental Health Services – Coverage of Audio-only services (Section #
II.D.1e)

Description of CMS Proposal or Request for Comment:
CMS proposes to reimburse for audio-only telehealth services, when a beneficiary is not capable
of using, or does not consent to, the use of two-way, audio/video technology) when used for
telehealth services for the diagnosis, evaluation, or treatment of mental health disorders
furnished to established patients in their homes.

PCC Comment:
PCC supports the use of audio-only technology to ensure access to behavioral health care
services and encourages this to be applied to mental health and substance use disorders.
Although in-person care or audio-video care is preferred over audio-only care, there are too
many situations when audio-only care is the only option for patients. As parts of the country
struggle with broadband connectivity and smartphone capabilities to support video visits,
particularly in rural and economically disadvantaged communities, CMS should allow telephone
E/M services to support these communities in their efforts to care for patients.

Audio-only technology remains a necessary tool in behavioral health care. To better inform
CMS and primary care clinicians as to optimal use of audio-only services, CMS could consider
an audio-only claims coding modifier so that it can be used to track utilization and conduct
outcomes and effectiveness research regarding audio-visual and audio-only tele-mental health
services. Specific attention should be given to outcomes and disparities across vulnerable

populations and across settings of care, and CMS should make every effort to limit any burden on practices associated with such a modifier. Evaluation of audio-only services would be beneficial to demonstrate quality and efficacy for behavioral health. Regulatory agencies should also evaluate quality standards, and protections against potential fraud, waste, and abuse.

5. Medicare Shared Savings Program – Addressing the Rural Glitch (Section # III.J.6b)

_Description of CMS Proposal or Request for Comment:_
CMS seeks comment on, but doesn’t formally propose changes yet, to the regional adjustment of MSSP benchmarks. Specifically, CMS requests feedback on how to account for the removal of ACO-assigned beneficiaries from the regional reference population, which is used to determine the regional portion of the spending benchmarks.

_PCC Comment:_
Primary care has played an important role in the quality improvements and cost savings produced by the Medicare Shared Savings Program. PCC’s 2018 Evidence Report, _Advanced Primary Care: A Foundation of Successful ACOs_, included a literature review and data analysis. This Evidence Report found that Accountable Care Organizations (ACOs) with a higher proportion of physicians with patient-centered medical home experience were more likely to produce savings and demonstrated higher quality scores. However, problems like the rural glitch make it more difficult to achieve success and sustain participation by ACOs.

PCC greatly appreciates CMS’ attention to this problem. To achieve shared savings, MSSP ACOs must have a level of Medicare Part A and B spending for attributed beneficiaries that is below a benchmark, based in part on regional Fee-for-Service Medicare spending. However, when an ACO successfully reduces spending for its beneficiaries, it thereby reduces regional fee-for-service Medicare spending. This further ratchets down the benchmark for ACOs and may incent them to exit the program.

CMS should take the opportunity to fix the rural glitch by making formal regulatory changes to remove attributable beneficiary costs from the regional benchmarks. We encourage CMS to implement these changes as soon as possible. In addition, we urge CMS to similarly exclude attributable beneficiary costs from regional benchmarks used in other Medicare ACO demonstrations, including the Global and Professional Direct Contracting Model.

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18 Primary Care Collaborative. _Advanced Primary Care: A Key Contributor to Successful ACOs_. August 2018. [https://www.pcpcc.org/resource/evidence2018](https://www.pcpcc.org/resource/evidence2018)
6. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) (Section # IV.A.1c)

*Description of CMS Proposal or Request for Comment:*
CMS requests public input for planning purposes for its planned transition to digital quality measurement, including the use of Fast Healthcare Interoperability Resources (FHIR) in physician quality programs.

*PCC Comment:*
The shift to digital quality measures (dQMs) has potential to reduce measurement burden and allow primary care practices to focus their energy on promoting patient health, not check-the-box metrics. Digitizing and automating the processes related to quality reporting, management and improvement can result in better measures, better measurement systems and better data—while dramatically reducing burden. By building data collection into clinician workflows, dQMs can reduce what is currently additional and separate work to collect quality data, freeing clinicians to focus on patient care. However, the agency’s approach to implementation will determine whether the promise of dQMs translates into reality.

We encourage CMS to emphasize flexibility as it moves forward with the transition to digital measures. Primary care practices, especially those serving low-income communities, communities of color and communities burdened by high rates of disease such as COVID-19, must receive the time, support and assistance needed to make the transition successfully to digital measurement. The selection of dQMs should also prioritize health equity by focusing on those “high-impact” measures where evidence shows additional access to care can improve quality outcomes and reduce disparities (e.g., heart failure, behavioral health). To ensure that any final policy with respect to dQMs or FHIR can be successful with primary care practices across a variety of communities, we encourage CMS to consider an additional 30- or 60-day comment period prior to finalizing any recommendation.

7. Diabetes Prevention Program Expanded Model (Section # IV.L)

*Description of CMS Proposal or Request for Comment:*
CMS proposes elimination of ongoing maintenance sessions (year 2) from Medicare DPP for beneficiaries who start their MDPP on or after January 1, 2022, redistribution of a portion of the payment from the ongoing maintenance sessions to the core and core maintenance session performance payments and permanent waiver of the supplier application fee.

*PCC Comment:*
PCC strongly supports strengthening the ongoing partnership between primary care and public health.\textsuperscript{19} The Diabetes Prevention Program is a first-of-its-kind effort by Medicare to support that partnership.

The National Diabetes Prevention Program Lifestyle Change Program is a proven, cost-saving public health intervention to reduce or delay risk of type 2 diabetes in those at risk. It can be delivered in a primary care setting or by community-based organization. The benefit is available without cost-sharing to beneficiaries. Unfortunately, only 27 percent of the more than 1000 eligible CDC-recognized organizations and only 3600 out of an estimated 15.3 million beneficiaries are participating in Medicare DPP.

Broader Medicare DPP supplier availability is needed to ensure primary care teams can help beneficiaries address diabetes risk. Aligning the Medicare benefit duration with CDC guidelines, restructuring the payment and waiving the application fee are each reasonable steps to promote supplier participation. Unfortunately, as proposed, the total maximum payment amount in the restructured, one-year program is less than that available under the two-year program. To ensure beneficiaries can access this proven diabetes prevention intervention, we urge CMS to ensure the finalized maximum payment is equal to the previous total.

Additionally, we are concerned about the end of virtual access to Medicare DPP following the Public Health Emergency. CMS should utilize the full range of its authorities to ensure Medicare coverage for all the CDC-recommended National DPP delivery modalities: in person, virtual and distance learning.

8. Closing the Health Equity Gap in CMS Clinician Quality Programs (Section IV.A.1d)

Description of CMS Proposal or Request for Comment:
CMS requests information regarding the future potential stratification of quality measure results by race and ethnicity and improving demographic data collection.

\textit{PCC Comment:} 
Stratifying quality measures by race and ethnicity is a critical step to ensure value-based care initiatives focus on health equity and reducing inequities. We agree that self-reported data with respect to race and ethnicity is the gold standard and should continue to be the model for obtaining race and ethnicity data. PCC supports moving toward stratifying performance and outcomes measures by self-reported race, ethnicity, primary language, geographic location, socioeconomic status, gender identity, sexual orientation, age and ability status.

However, PCC is concerned by CMS’s consideration of broader use of algorithms that indirectly estimate race and ethnicity. The limitations in the reliability and accuracy of the estimated data could produce significant underestimates or overestimates within a data set of race and ethnicity information.\textsuperscript{20} For example, estimated race in a Medicare home health care population both overestimated and underestimated the prevalence of dementia and diabetes when compared to the gold standard self-reported race. A recent Workshop identified ethical risks associated with advanced estimation methods that could result in inaccurate estimates and misleading conclusions that may cause harm.\textsuperscript{21} PCC is concerned that indirect estimation would exacerbate existing disparities for Black, Indigenous and other communities of color. The limitations of these indirect estimation methods could be magnified when applied to smaller minority groups including American Indian/Alaskan Native and multi-racial people for whom indirect estimates are less accurate.

Instead, CMS should adjust standards for CMS quality programs to support collection of disaggregated data. We anticipate such a change will encourage EMR vendors to update their products accordingly.

At the same time, a careful approach to implementation of such standards will be key to their success. Working with other agencies and the industry, CMS should strive to minimize burden on primary care associated with additional data collection requirements and reduce or eliminate the costs associated with updating EMR products. CMS should ensure that primary care practices are provided adequate support and training in the appropriate collection of self-reported data based on best available practices. For example, primary care teams might be trained to explain how self-reported information will be used to improve care quality, that it will be protected, and that it will not be shared with Immigrations and Customs Enforcement or Child Protective Services. Having taken these steps, CMS should then work to expand data collection to a broader set of self-reported characteristics that include primary language, geographic location, socioeconomic status, gender identity, sexual orientation, age and ability status.

9. RFI on Vaccine Administration Services (Section # II.J)

Description of CMS Proposal or Request for Comment:


CMS requests feedback on how CMS should update the payment rate for administration of preventive vaccines under Medicare Part B. CMS notes that payment for vaccine administration has decreased by more than 30 percent since 2015. In 2015, the national payment rate for these services was $25.51 while in 2021 the national payment rate is $16.94. CMS also requests feedback on the current $40/dose payment for COVID-19 vaccination.

**PCC Comment:**
Despite some progress in vaccination rates prior to the pandemic, MedPAC reports that rates continued to lag public health goals established by CDC and documented major gaps and disparities in vaccinations. For example, vaccination rates for Black and Hispanic beneficiaries remain consistently lower than White beneficiaries.\(^{22}\)

Alarming evidence also suggests that immunization rates for non-COVID conditions dropped significantly during the COVID-19 pandemic and have not rebounded to pre-pandemic levels.\(^{23}\)

Higher reimbursement is an indispensable part of the solution. Studies show that higher vaccine administration payment rates are associated with higher rates of utilization.\(^{24}\) In a recent survey of physician practices, 80 percent of respondents indicated increasing vaccine administration payment rates would help to overcome vaccination barriers and costs created by the pandemic.\(^{25}\)

As a first step, PCC supports Medicare’s adoption of the spring 2021 Relative Value Update Committee’s recommendations for vaccine administration payment codes in CY 2022. Then, moving forward, we recommend CMS consider whether a more innovative payment methodology would more effectively capture the value of vaccinations and optimize vaccination rates for Medicare beneficiaries than the traditional cost-based payment methodology.

PCC supports the special $40 per dose payment rate for COVID-19 vaccination administration. The $40 per dose payment rate more accurately covers the costs that many practices incur by offering the COVID-19 vaccine. Unique costs include ultra-cold storage requirements, longer

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\(^{24}\) Tsai, Y. (2018). Payments and Utilization of Immunization Services Among Children Enrolled in Fee-for-Service Medicaid. *Medical Care, 56*(1), 54. [https://doi.org/10.1097/MLR.0000000000000844](https://doi.org/10.1097/MLR.0000000000000844)

counseling time, the use of clinic space for the 15-minute observation time and additional reporting requirements.

The need to build vaccine confidence is critical in the fight against COVID-19; therefore, Medicare should support counseling services to patients who are seeking to mitigate their risk for COVID-19 infection. Specifically, we encourage CMS to make payment and coverage available for CPT code 99401 (Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure). We encourage CMS to temporarily make payment available for this code through at least December 31, 2023 and waive the face-to-face requirement associated with this service.

Thank you for this opportunity to share our comments. Please contact PCC’s Director of Policy, Larry McNeely (lmcneely@thepcc.org) with any questions.

Sincerely,

Ann Greiner
President & CEO
Primary Care Collaborative
## PCC Executive Members

Below is a list of the Primary Care Collaborative’s executive members that pay dues to the organization and support its mission. Membership does not indicate explicit endorsement of this letter.

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