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September 10, 2021

VIA ELECTRONIC SUBMISSION

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1751-P
Baltimore, MD 21244-1850

Dear Administrator Brooks-LaSure:

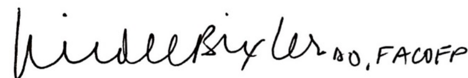
On behalf of the American College of Osteopathic Family Physicians (ACOFP), we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Calendar Year (CY) 2022 Physician Fee Schedule and Quality Payment Program Proposed Rule ("Proposed Rule").

ACOFP is the professional organization representing more than 18,000 practicing osteopathic family physicians, residents and students throughout the United States who are deeply committed to advancing our nation's health care system by improving health care delivery and outcomes and ensuring that patients have access to high-quality care.

In general, we feel the Proposed Rule would help improve care delivery and expand access to care. However, there are also some proposals we hope CMS will reconsider or adjust to better support family physician practices. For example, the proposal to transition to MIPS Value Pathways should be slowly implemented and ensure that no new reporting requirements are placed on family physicians.

Our full comments are detailed on the following pages. Thank you for the opportunity to share our feedback with you. Should you need any additional information or if you have any questions, please feel free to contact ACOFP at advocacy@acofp.org or (847) 952-5100.

Sincerely,



Nicole Bixler, DO, MBA, FACOFP
ACOFP President

1. Comments to Proposed Changes to the Physician Fee Schedule

Extending Category 3 Telehealth Services Through CY 2023

CMS has added 135 new services to the Medicare telehealth list that are available during the COVID-19 public health emergency (PHE) on a Category 3 basis. CMS describes Category 3 services as those that are temporarily available during the PHE and are likely to have a clinical benefit when furnished via telehealth, but there is not yet sufficient evidence to permanently add such services to the Medicare telehealth list. Currently, Category 3 services will be removed from the list after the PHE ends.

CMS is proposing to revise the timeframe for the availability of services added on a Category 3 basis. Specifically, CMS is proposing to retain all Category 3 Medicare telehealth services through CY 2023. CMS hopes this proposal would provide stakeholders sufficient time to collect information regarding utilization of these services and provide stakeholders time to develop evidence to support the permanent addition of these services to the Medicare telehealth list.

According to the U.S. Department of Health and Human Services, primary care telehealth utilization increased by 350 percent during April 2020, largely due to CMS's telehealth regulatory flexibilities and expanding the available telehealth services.[1] These regulatory changes have been critical to ensuring that seniors and other vulnerable populations have access to care during the COVID-19 pandemic and remain necessary as providers respond to the delta variant. Family physicians are also finding that telehealth is a critical tool for treating patients with long-lasting health conditions from COVID-19 ("long-haulers") and those with chronic conditions that are at risk of serious complications from COVID-19.

ACOFP supports CMS's proposal to include Category 3 services on the Medicare telehealth list through CY 2023. This will provide stakeholders with sufficient time to gather data and determine which services should be added to the list on a permanent basis. Additionally, it will provide certainty for patients and providers that they can continue to furnish and receive Category 3 telehealth services through 2023.

For future rulemaking, CMS should consider expanding access to audio-only telehealth services. We understand the Proposed Rule would implement the Consolidated Appropriations Act, 2021 (CAA) to permanently allow audio-only telehealth for mental health services. CMS should consider making available on a permanent basis primary care services delivered via audio-only technology and ensure that such services are reimbursed at the same rate as face-to-face encounters.

Split (or shared) E/M Visits

CMS is proposing to make several changes to their policies on evaluation and management (E/M) split (or shared) visits. These visits occur when a physician and non-physician practitioner (NPP) each personally perform a portion of an E/M visit. In particular, CMS is proposing that the practitioner who provides the substantive portion of the visit (more than half of the total time spent) would bill for the visit.

While we recognize using time to determine the substantive portion of an E/M split (or shared) visit would provide a clear rule for CMS and providers to follow, we urge CMS to allow for medical decision-making (MDM) to be available for a provider when determining the "substantive portion" of an E/M visit. In certain visits, MDM may be the most critical component of the care delivered during the visit. In these instances, the billing practitioner should have the option of selecting either MDM or time when determining the substantive portion of a visit.

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[1] *Medicare Beneficiary Use of Telehealth Visits: Early Data from the Start of the COVID-19 Pandemic*. Pg. 5. July 28, 2020. Accessible here: https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//198331/hp-issue-brief-medicare-telehealth.pdf

We also note that CMS sub-regulatory guidance allowed providers to use MDM to determine the substantive portion of an E/M split (or shared) visit until it was withdrawn due to a technical interpretation of the law.[2] CMS should continue to allow MDM to ensure certainty in its billing procedures and avoid practice disruptions.

Primary Care Exception for Teaching Physicians

CMS is proposing to clarify that teaching physicians can use time to determine an E/M visit level, but when a teaching physician is not present—per the primary care exception—only MDM can be used to select a level. Currently, the list of services that fall under the primary care exception contain all of the office/outpatient E/M visit levels. When the COVID-19 PHE ends, levels four and five E/M visits will no longer be included under the primary care exception. CMS is proposing to use only MDM to select an E/M level under the primary care exception to guard against the excessive billing of high-level E/M services by residents.

We recommend allowing the teaching physician to be able to use either time or MDM under the primary care exception. Based on our experience, teaching physicians are closely monitoring residents and are not abusing the primary care exception to access a higher-level E/M visit. By allowing the use of time, CMS would be continuing to provide flexibility for the teaching physician during the COVID-19 PHE. Also, using only MDM—as proposed by CMS—may create incentives for physicians to quickly move residents from patient to patient rather than furnishing the appropriate clinical care.

Vaccine Administration Request for Information

Since 2015, Medicare payment rates for physicians and mass immunizers for administering certain preventative vaccines (flu, pneumonia and Hepatitis B) have decreased by nearly 30 percent[3] while, at the same time, studies have found that vaccines are one of the most cost-effective healthcare interventions.[4] This is especially pronounced as the COVID-19 vaccines have demonstrated incredible efficacy. The Centers for Disease Control and Prevention (CDC) recently found that 96 percent of fully vaccinated (Pfizer-BioNTech and Moderna) adults aged 65–74 avoided hospitalization after contracting COVID-19.[5] The data is clear that vaccines are incredibly important to public health and very cost effective, yet CMS has consistently reduced payment rates.

In recognition of low vaccine administration payment rates, CMS is requesting feedback on various questions and issues related to vaccine payment. CMS is especially interested in understanding the costs (e.g., labor or resources used) associated with furnishing Medicare Part B-covered preventative vaccines, as well as suggestions for policy changes to improve vaccine payment. In response to these requests, we highlight family physician-focused costs and considerations that are associated with vaccine administration and how primary care providers are key to improving vaccination efforts and, therefore, worth additional investment from CMS.

There are many costs associated with furnishing vaccine services that are shouldered by family physicians. For each vaccine administration, there are costs associated with documenting the vaccine services in the electronic health record (EHR) system, storing the vaccine, administering the vaccine, verifying the procedure and billing the procedure. As for COVID-19 vaccines, the costs associated with storage are even greater given

[2] Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements. 86 Fed. Reg. 39204-39205 (July 23, 2021)
[3] Id. at 39221
[4] Vanessa Remy, et. Al., Vaccination: the Cornerstone of an Efficient Healthcare System. J Mark Access Health Policy. (August 2015). Available here: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4802703/
[5] Effectiveness of COVID-19 Vaccines in Preventing Hospitalization Among Adults Aged >65 years – COVID-NET, 13 states, February – April 2021. (August 2021). Available here: https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e3.htm?s_cid=mm7032e3_w

that most authorized or approved products require cold storage. Furthermore, family physicians are required to not only input the vaccination in the EHR but are also required to report to state vaccine registries. Lastly, patients are required to sequester for 15 minutes to ensure there are no side effects. This takes up space that could otherwise be used for providing care to other patients.

The costs and reporting requirements associated with vaccine administration create a financial disincentive for family physicians to provide them to their patients. For example, family physicians spend $17 on each vaccine administration[6] while Medicare's average physician reimbursement rate is approximately $16.[7] Small, solo, and independent family practices already operate on tight margins and do not have the same resources as hospitals or large physician practices to absorb losses from vaccine administrations. Furthermore, many family physician practices have limited—if any—administrative staff, but are required to meet numerous reporting requirements across CMS programs, as well as state vaccine reporting requirements. While large pharmacies or provider organizations may have the administrative resources to meet these reporting requirements, they are difficult for family physician practices given limited resources.

We also note that family physicians are key to helping address COVID-19 vaccine hesitancy. Studies are showing that although American adults are eligible for a COVID-19 vaccine, many are not getting it due to vaccine hesitancy.[8] However, 15 percent of unvaccinated individuals indicated they would be more likely to receive the vaccine if recommended by their provider.[9] We believe this is because providers, particularly family physicians, have close relationships with their patients, positioning them to serve as a trusted resource of information on COVID-19 vaccines.

As CMS considers new payment methodologies for vaccine administration, we urge CMS to develop a payment rate that incorporates the costs described above associated with furnishing vaccine services. An appropriate payment rate should at a minimum ensure family physicians are made whole. Family physicians should not experience a financial loss from providing vaccine services to beneficiaries. CMS should consider basing vaccine payment rates on average commercial rates or setting the payment rate based on the 2015 Medicare rate, adjusted for inflation up to 2022, and provide an incremental increase for each subsequent year. Additionally, CMS should prioritize physician-administered vaccines since family physicians are a powerful tool in addressing vaccine hesitancy.

Opioid Treatment Program (OTP) Payment Policy

CMS is proposing to allow OTPs to furnish counseling and therapy services via audio-only interaction after the COVID-19 PHE when audio/video communication is not available to the beneficiary. CMS also proposes the requirement of OTPs to use a claim modifier when furnishing additional services via audio-only technology and provide a rationale for why audio-only was used in the medical record.

ACOFP supports the use of audio-only technology, especially for beneficiaries that do not have access to broadband or audio/visual technology. Therefore, ACOFP is in support of this proposal. This proposal will ensure OTPs can reach rural or urban beneficiaries that do not have access to broadband or audio/visual

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[6] Yarnoff, Benjamin. Estimating the Costs and Income of Providing Vaccination to Adults and Children. Medical Care. (June 2019). Available here: https://journals.lww.com/lww-medicalcare/Abstract/2019/06000/Estimating_the_Costs_and_Income_of_Providing.5.aspx (Does not include costs associated with COVID-19 vaccines).

[7] Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements. 86 Fed. Reg. 39222 (July 23, 2021)

[8] Scott Ratzan, M.D., M.P.A., et al. Missing the Point – How Primary Care Can Overcome COVID-19 Vaccine "Hesitancy." May 5, 2021. Available at: https://www.nejm.org/doi/full/10.1056/NEJMp2106137

[9] Id.

technology. This also will help maintain or improve access for many beneficiaries struggling with opioid use disorder.

Drug Enforcement Agency (DEA) Enrollment Proposal

CMS has existing authority to deny a physician's Medicare enrollment if his or her DEA certificate of registration to dispense controlled substances is currently suspended or revoked. CMS is proposing to expand these authorities to include situations where the physician surrenders his or her DEA certificate to an order to show cause (i.e., at the initiation of a formal proceeding to revoke or deny certification).

Unfortunately, some physicians have inappropriately prescribed opioid prescription drugs, which has contributed to the ongoing opioid epidemic. Abusive opioid prescribing behavior by physicians is inexcusable, and ACOFP believes CMS should use whatever tools necessary to punish these physicians. However, we also recognize that prescription opioids have a clinical benefit for patients suffering from chronic pain or other health conditions. CMS must always balance the need to discourage dangerous prescribing behavior with ensuring patients have access to needed medication.

If this proposal is finalized, we urge CMS to carefully consider the facts of each case before denying a provider's Medicare enrollment. There could be reasons for a physician to surrender his or her DEA certificate prior to an order to show cause that may not merit a denial. Overall, we want to ensure that CMS is not disenrolling innocent physicians to the detriment of beneficiaries.

Exempting COVID-19 Vaccines from Certain Self-Referral Rules

Currently, COVID-19 vaccines are not considered "designated health services" (DHS) for purposes of the physician self-referral law (also known as the Stark Law) but would be considered DHS if Medicare begins to pay for COVID-19 vaccines, unless an exception could apply. CMS is proposing to amend an exception to the self-referral law to ensure COVID-19 vaccines could fall under the exception if certain conditions are met. Specifically, CMS is amending regulations to state that a "mandatory frequency limit"[10] does not apply to a COVID-19 vaccine code during the time period that the vaccine is not subjected to a CMS-mandated frequency limit. In the Proposed Rule, CMS stated that expanding the exception would not pose a risk of program or patient abuse.

ACOFP agrees with CMS and is in support of this proposal. We do not foresee a significant risk to the Medicare program or patients by allowing COVID-19 vaccines to fall under the exception. Rather, we believe that this proposal would allow physicians to make referrals for vaccines without fear of violating the Stark Law and would more likely increase access to vaccines.

Health Equity Request for Information

The COVID-19 pandemic has underscored existing health disparities in the American health care system. Studies are showing that health and social factors between different racial and ethnic groups may increase risk of severe illness or death from COVID-19.[11] Health disparities are not limited to COVID-19. Studies show health disparities among racial and ethnic minorities for heart disease, maternal mortality, obesity and other

[10] Frequency limits determine the maximum number of times that Medicare will pay for a service for a particular beneficiary during a specific time period.
[11] Risk of Severe Illness or Death from COVID-19: Racial and Ethnic Health Disparities. CDC. December 10, 2020. Available here: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/disparities-illness.html#ref7

conditions.[12] Some studies have shown that racial and ethnic minorities are less likely to receive preventative care, which may be due to discrimination in health care settings.[13]

To help address health inequities, CMS is seeking feedback on ways it can improve data collection to measure and analyze disparities across its programs and policies. ACOFP applauds CMS's efforts to address health disparities. As an organization, we are committed to ensuring all patients—regardless of their race, religion, sex or sexual identity—have access to high-quality care and are free from discrimination.

While ACOFP strongly supports addressing racial and ethnic disparities, we urge CMS to develop meaningful data collection policies that do not overburden health care professionals. Providers should not be shouldered with burdensome reporting requirements that make it difficult to furnish care for patients. Instead, CMS should develop data collection policies that have a clear use and can be easily incorporated into physician practice workflow.

2. Comments to the Proposed Changes to the Quality Payment Program

MIPS Value Pathways Transition

CMS is planning to transition away from the Merit-based Incentive Payment System (MIPS) to MIPS Value Pathways (MVPs) in order to "improve value, reduce burden, inform patient choice in selecting clinicians and facilitate movement into Advanced Payment Models."[14] MVPs are designed to focus on a specific condition or specialty. In the Proposed Rule, CMS is proposing an initial set of MVPs that will be available for reporting in CY 2023, including an MVP that is relevant for family physicians. The agency intends to propose additional MVPs to cover more specialties and conditions over the coming years. CMS is also considering sunsetting traditional MIPS by 2027, and beginning in 2028, CMS is proposing that MVP reporting would be mandatory.

We are encouraged that CMS is committed to improve provider and patient experience in the Medicare program. As the agency is aware, physicians have been frustrated with the MIPS program. Many ACOFP members have found the program overly burdensome, confusing and not linked to patient care.

Small, solo and independent family physician practices have been particularly frustrated with the program since they have limited resources to meet the many requirements of MIPS. Family physicians have also been forced to make significant practice changes and investments in EHR systems to ensure they are complying with the MIPS program. Our members have also spent considerable time keeping up with annual updates and policy changes since the program was implemented.

We appreciate the slow transition away from MIPS to MVPs. This will help physicians develop a familiarity with the program. We are also encouraged that physicians will be able to report on MVPs as early as 2023 but are not required to do so. Some physicians may be in a position to begin reporting on MVPs in 2023 and gain experience in the program. However, many family physicians only recently developed familiarity with MIPS and are reluctant to start over with a new program. They are also concerned that MVPs will require updates to

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[12] Baciu A, Negussie Y, Geller A, et al., National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Communities in Action: Pathways to Health Equity. Washington (DC): National Academies Press (US); 2017 Jan 11. Available here: https://www.ncbi.nlm.nih.gov/books/NBK425844/

[13] Hostetter, Martha and Klien, Sarah. In Focus: Reducing Racial Disparities in Health Care by Confronting Racism. Commonwealth Fund. Available here: https://www.commonwealthfund.org/publications/2018/sep/focus-reducing-racial-disparities-health-care-confronting-racism

[14] Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements. 86 Fed. Reg. 39337 (July 23, 2021)

their EHR systems and new changes to their practices. Small, solo and independent practices are particularly concerned about the transition given their limited resources to comply with a new program.

We urge CMS to closely monitor the transition to MVPs and be prepared be delay its implementation. If there is low participation in MVPs in the years close to 2028, CMS should consider delaying the program to ensure that providers are prepared and have experience before making it mandatory. Additionally, if physicians are reporting issues with the transition—whether through lack of relevant MVPs or measures within those MVPs or the inability for some practices to transition to MVPs—CMS should delay the beginning date. In order for the MVP program to be successful, there must be a deliberate transition that allows providers to become familiar and comfortable with the program.

Lastly, we urge CMS to ensure that the MVP program will not require physicians to make unreasonable updates to their EHR systems or practice changes. Providers should be able to maintain their current practices and not spend additional dollars on their EHR systems. ACOFP members are very concerned that they will have to make continual EHR updates and changes to comply with shifting CMS programs. To the extent possible, the MVP program should not force providers to invest additional dollars into their EHR systems.

MIPS Value Pathways Reporting

In general, MVPs are intended to have similar reporting requirements as traditional MIPS. MVPs would maintain the quality, cost and improvement activities categories, while also including a "foundational layer" for each MVP that would incorporate a population health measure and the promoting interoperability category. CMS also stated that MVPs would be a conduit for capturing granular data while reducing reporting burden.

We appreciate CMS's efforts to design MVP reporting requirements similar to MIPS. This will help ease the transition to MVPs. However, each reporting category must include measures that are relevant to the MVP and the provider specialty that is most likely to report on that MVP. CMS should use the transition period to develop relevant and meaningful measures for MVPs. Under MIPS, many providers have complained that quality measures are not relevant to patient care or their specialty. With the deliberate transition to MVPs, CMS should work with stakeholders and other policy experts to identify and develop meaningful measures for provider specialties that will participate in the program.

ACOFP members are also concerned that MVPs will ultimately increase reporting burden. While CMS intends the MVPs to reduce burden, the agency is simultaneously expecting providers to report granular data through MVPs. We urge CMS to not increase reporting burden through the MVP program. Family physicians are already overly burdened with reporting requirements, and CMS should avoid time-consuming data reporting efforts. Rather than placing further reporting burdens on physicians, CMS should consider gathering comprehensive data from existing datasets and entities. For example, CMS could gather data from state public health departments, health information exchanges and/or CDC datasets for public health measures included in the MVP foundational layer. Overall, providers will be reluctant to transition to MVPs if they believe it will increase reporting burden, so CMS should avoid new reporting mandates as much as possible.