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October 5, 2020

VIA ELECTRONIC SUBMISSION

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
P.O. Box 8016
Washington, D.C. 21244-8016

Dear Administrator Verma:

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) 2021 Physician Fee Schedule (PFS) and Quality Payment Program (QPP) 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 receive high-quality care.

As an organization of primary care physicians, we appreciate CMS' efforts to prioritize primary care in the PFS proposed rule. We are encouraged by the proposals to make permanent or extend certain telehealth services and urge you to finalize the revaluation of the evaluation and management (E/M) services. However, we are concerned that elements of the proposed rule shift care delivery away from primary care physicians. We understand the COVID-19 pandemic is an unprecedented public health crisis, but seniors must have access to the highest quality care, which is delivered by physician-led care teams.

Our full comments are detailed in 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,



Robert C. DeLuca, DO, FACOFP *dist.*
ACOFP President

1. Comments to Proposed Changes to the Physician Fee Schedule

ACOFPP appreciates CMS' work to expand telehealth services to respond to the COVID-19 pandemic and improve the health care system while also recognizing the importance of primary care by revaluing certain E/M codes. The health care delivery system must prioritize patient care and quality outcomes by supporting primary care physicians. This rule takes significant steps in supporting family medicine physicians to deliver high-quality care to patients across the country. Although we have concerns that some proposals would set a precedent that would shift primary care services away from family medicine physicians to other providers, we are generally in support of the proposed rule especially because its proposed policies would be helpful when a face-to-face encounter is not possible.

Proposed Telehealth Services

In response to the COVID-19 public health emergency (PHE), CMS loosened its telehealth rules and expanded the amount of telehealth services that are reimbursable by Medicare. These changes have been critical for seniors, especially during the early months of the outbreak when in-person visits dropped dramatically. We are encouraged that CMS is proposing to permanently or temporarily extend many telehealth services. While we recognize that a face-to-face evaluation is the gold standard of care delivery, we generally are in favor of increasing the availability of telehealth services, especially during the COVID-19 PHE to avoid exposure to the disease for seniors and providers alike.

According to the Department of Health and Human Services (HHS), telehealth utilization increased by 350 percent during April 2020,¹ and although utilization is beginning to level off as in-person visits rebound, we are experiencing a paradigm shift in care delivery that relies more on telehealth. It is critical CMS monitor utilization and quality trends to ensure telehealth is being used appropriately and provides quality outcomes. We agree with you that the gold standard of health care is a face-to-face visit and that telehealth cannot replace in-person services. Therefore, we encourage the Agency to monitor and assess the use of telehealth and revise policies to ensure patient care is not compromised.

We are also concerned about the potential for abuse and fraudulent billing with the expanded flexibilities for telehealth. Some bad actors may take advantage of the COVID-19 PHE and unnecessarily overutilize telehealth or misrepresent their telehealth utilization. This not only is an abuse of taxpayer dollars but could increase out-of-pocket costs for beneficiaries. CMS should work to address fraud and abuse without increasing administrative burden for physicians especially for small and solo physician practices. We also encourage CMS to distinguish between fraud and abuse and honest or unintended errors by the physician.

In this proposed rule, CMS requested comment on whether certain CPT codes should be added to the Medicare telehealth list. We believe the emergency department visit codes levels 4-5 (CPT codes 99284-99285) are examples of services that are not appropriate for telehealth. Given the

¹ Issue Brief. *Medicare Beneficiary Use of Telehealth Visits: Early Data from the Start of the COVID-19 Pandemic*. July 28, 2020. Accessible at https://aspe.hhs.gov/system/files/pdf/263866/HP_IssueBrief_MedicareTelehealth_final7.29.20.pdf

detailed examination requirements and complexity of the medical decision-making associated with these codes, we believe it is more appropriate that these types of services remain in the emergency department rather than furnished via telehealth. We are also concerned that the radiation management treatment services may not be appropriate for telehealth. Overall, when a service requires highly specialized treatment and/or the patient has severe acuity that demands immediate hands on attention, telehealth should not be used. We also recognize that telehealth is more appropriate as a general matter for established patients. Initial visits for higher level complex services should be conducted in-person.

Lastly, we urge CMS to provide appropriate reimbursement for telehealth services. The COVID-19 pandemic has severely impacted small, solo, and rural practices. Many are relying on telehealth to ensure their practice does not close and they can continue to serve their communities. There is already a shortage of primary care physicians in this country, with rural and medically underserved areas most impacted. Therefore, CMS must provide appropriate telehealth reimbursement rates that will help physician practices remain open so that they can continue to serve as an access to health care.

Audio-Only Telehealth Visits

One important flexibility CMS has offered during the COVID-19 PHE is the ability for physicians to provide services via audio-only telecommunications technology and to be reimbursed as telehealth services. In the proposed rule, CMS requested feedback on whether these audio-only visits should continue to be paid. We strongly recommend continuing to reimburse audio-only telehealth visits and maintaining the increased reimbursement rates established in the April 30, 2020 Interim Final Rule with Comment Period.²

We believe CMS' audio-only telehealth policy is appropriate when the beneficiary does not have access to audio-visual technology. ACOFP members – practicing in both rural and urban areas – have many patients who do not have access to audio-visual technology, broadband internet, or the technical skills to operate certain technology. The availability of audio-only telehealth especially has been essential in tribal areas where there is limited broadband internet access or audio-visual technology. In these cases, audio-only telehealth visits are the best option to ensure seniors have access to care while minimizing exposure to COVID-19. The increased payment rates have also helped providers maintain access for their patients. The COVID-19 pandemic has demonstrated that audio-only visits are an appropriate care delivery pathway to ensure beneficiaries have access to their family medicine physician and should be sustained. Therefore, we strongly urge you to reimburse audio-only visits as telehealth E/M services during the COVID-19 PHE at levels comparable to in-person visits when an in-person visit is not possible.

Once the COVID-19 pandemic ends, we do not believe the audio-only visits will be necessary, but believe its current necessity highlights greater systemic problems related to the lack of access to

² *Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program.* 85 FR 27550. Available at <https://www.federalregister.gov/documents/2020/05/08/2020-09608/medicare-and-medicaid-programs-basic-health-program-and-exchanges-additional-policy-and-regulatory>

telehealth services in many communities. We are encouraged that HHS is exploring efforts to increase access to such services in rural areas and offer our support in those efforts.

Definition of Direct Supervision

CMS is proposing to extend its interim policy that the definition of direct supervision includes the virtual presence of the supervising physician using interactive audio-visual real-time communications technology. We support extending this interim policy with appropriate guardrails.

Physicians should be able to use their clinical judgement regarding the types of patients or services that require their physical presence for purposes of direct supervision. If the physician believes it is best for the patient to avoid exposure to COVID-19 and the patient has a condition that would not require the physical presence of the supervising physician, the physician should be able to use audio-visual technology for the purposes of direct supervision. In our experience, states have developed policies that are most appropriate for physicians and other medical professionals to ensure adherence to the requirement that the supervising physician be readily available to directly supervise as needed. We recommend that CMS defer to states to ensure there are appropriate guardrails in place for direct supervision. In addition, this flexibility will sustain access to care during and beyond the COVID-19 pandemic, while also maintaining the integrity of the physician-led care team model.

While we understand that Medicare payment is not allowed for services provided outside the United States,³ we urge CMS to ensure that this proposal is not abused by bad actors. We recommend CMS provide clarifying language in the final rule to ensure the supervising physician must be in the United States when using audio-visual technology for purposes of direct supervision.

Scope of Practice Provisions

CMS is proposing several policies that impact clinician scope of practice. In particular, CMS is proposing to make permanent a policy to allow nurse practitioners to bill for services incident to their professional services for new and established patients when assessing and collecting specimens for COVID-19 testing, as well as allowing non-clinicians to perform more telehealth services and supervising diagnostic tests. We understand that during the COVID-19 pandemic patients need access to care. However, we fear the trend of shifting primary care services to non-physician practitioners undermines patient care in the long term. Non-physician practitioners, who lack comparable training, only should be utilized under the supervision of a physician when there is a genuine lack of availability of primary care physicians.

In the proposed rule, CMS stated the scope of practice provisions were implemented to align with the Executive Order (EO) on *Protecting and Improving Medicare for Our Nation's Seniors*. Section 5(b) of the EO contains overly broad language that we believe will raise costs for Medicare

³ Section 1862(a)(4) of the Social Security Act and 42 CFR § 411.9(a)

and risk patient health. We previously expressed⁴ our concerns with expanding non-physician scope of practice and reiterate our concerns below.

Physician-led care teams are the gold standard for care delivery; non-physician-led care teams are not equivalent. Non-physician practitioners do not have the same training or education as physicians. A family medicine physician will spend approximately 18,900 more hours on education and training than other mid-level practitioners.⁵ Decades of evidence has shown that physicians are better positioned to deliver high-quality care because of their demanding education and professional training requirements. Since physicians provide higher quality care, beneficiaries experience better health outcomes and Medicare realizes overall savings from healthier seniors.⁶ We therefore encourage CMS to recognize that physicians provide the highest quality primary care and urge the Agency to enact policies that support family medicine physician-led care teams.

Immunization Administration Services

CMS is proposing to revalue the immunization and administration codes (CPT codes 90460, 90471, and 90473) to better reflect the resources involved in furnishing these services. In light of the decreasing reimbursement rates for vaccinations, we are concerned this will create an access issue for seniors. ACOFP supports the revaluation as it is a step forward to improving access to immunizations for beneficiaries. With the COVID-19 outbreak, it is more important than ever to ensure seniors have access to vaccinations.

However, although the revaluation is an improvement from the status quo, it would only align vaccine administration reimbursement with the CY 2017 rates.⁷ We urge CMS to further recognize the resources and practice expense that will be associated with vaccine administration in 2021 given the COVID-19 pandemic. The costs associated with administering vaccines while limiting exposure to patients and staff will be considerable in 2021, and we hope CMS will recognize these new expenses in the final rule. Ideally, reimbursement should be based on actual vaccination costs and not limited to personnel time, proper storage, specialized equipment (i.e., electronic health

⁴ See ACOFP Letter to Administrator Seema Verma re: CMS solicitation of Feedback on EO #13890. Accessible at https://www.acofp.org/acofpimis/Acofporg/PDFs/Advocacy/ACOFP_Comments_EO_Scope_of_Practice.pdf

⁵ Primary Care Coalition. *Compare the Education Gaps Between Primary Care Physicians and Nurse Practitioners*. Texas Academy of Family Physicians, Texas Pediatric Society, and the Texas Chapter of the American College of Physicians. Available at <https://tafp.org/Media/Default/Downloads/advocacy/scope-education.pdf>

⁶ For example, see generally The Mayo Clinic Proceedings. *Comparison of the Quality of Patient Referrals From Physicians, Physician Assistants, and Nurse Practitioners*. Available at:

[https://www.mayoclinicproceedings.org/article/S0025-6196\(13\)00732-5/abstract](https://www.mayoclinicproceedings.org/article/S0025-6196(13)00732-5/abstract) (finding that primary care physicians have higher quality referrals); Journal of the American Medical Association. *A Comparison of Diagnostic Imaging Ordering Patterns Between Advanced Practice Clinicians and Primary Care Physicians Following Office-Based Evaluation and Management Visits*. Available at

<https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1939374> (finding that non-physicians order more expensive imaging services); and Journal of Nursing Regulation. *Prescribing Practices by Nurse Practitioners and Primary Care Physicians: A descriptive Analysis of Medicare Beneficiaries*. Available at: [https://www.journalofnursingregulation.com/article/S2155-8256\(17\)30071-6/fulltext](https://www.journalofnursingregulation.com/article/S2155-8256(17)30071-6/fulltext) (finding a higher number of prescriptions issued by nurse practitioners for moderate comorbidity groups).

⁷ See 85 Fed. Reg. 50163 (Aug. 17, 2020)

record systems and refrigeration), documentation, administration costs, and other related items and services.

Evaluation and Management Proposals

In the CY 2020 PFS final rule, CMS finalized a policy to adopt new coding, prefatory language, and interpretative guidance issued by the American Medical Association's (AMA) CPT Editorial Panel, which would be effective January 1, 2021. The CY 2021 proposed rule would largely align with the AMA's recommendation except for a refinement to clarify the times for which prolonged office/outpatient E/M visits can be reported and a revision to the times used for rate setting on the prolonged code. Lastly, CMS is proposing to increase the relative value units (RVUs) for many primary care-related codes.

We appreciate CMS' work to adopt policies intended to simplify the coding practice and align with current practices. Administrative burden is a significant issue for ACOFP members, especially for solo, small, and rural practices that do not have the resources to manage excessive paperwork requirements in the Medicare program. We are hopeful these policies will decrease administrative burden and allow physicians to treat more patients in a comprehensive manner and spend more time with complicated patients. Overall, we support the implementation of these policies and strongly urge CMS finalize them as proposed.

Many of our solo, independent, and rural members have been struggling to remain open and financially solvent. These practices do not have the resources that large physician groups or hospitals have to weather the economic downturn. As you know, once a primary care physician office closes in a community, it is very difficult to attract new physicians to serve that community. The new E/M valuation will provide additional resources to practices and help ensure they can serve patients in their communities.

Opioid Treatment Program (OTP) Proposals

CMS is proposing to add naloxone to the definition of opioid use disorder treatment services and allow opioid treatment programs (OTPs) to be paid under Medicare for naloxone. Additionally, CMS is proposing to adopt add-on codes for opioid antagonist medications. We support these policies.

The nation's opioid crisis has quietly worsened as the COVID-19 pandemic has dominated the country's attention. The AMA has stated that 40 states reported increases in opioid-related mortality⁸, and last year, the opioid epidemic killed over 72,000 Americans according to the Centers for Disease Control and Prevention.⁹ It is critical that the opioid crisis is not forgotten and that physicians have the tools to treat individuals with a substance use disorder (SUD). We also note that a majority of recent opioid overdose deaths—especially during the pandemic—are a

⁸ Issue Brief. *Reports of increases in opioid-related overdose and other concerns during COVID pandemic.* American Medical Association. Available at: <https://www.ama-assn.org/system/files/2020-09/issue-brief-increases-in-opioid-related-overdose.pdf>

⁹ 12 Month-ending Provision Number of Drug Overdose Deaths. Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

result of illegal fentanyl or heroin and unrelated to proper pain management utilizing prescribed opioids.

Naloxone is a proven lifesaving drug that can stop an opioid overdose. Allowing OTPs to issue naloxone and establishing the add-on codes will give OTPs one more tool to help individuals with SUDs.

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

MIPs Value Pathways

CMS is proposing to implement the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) through rulemaking as early as the 2022 performance period. While ACOFP appreciates CMS' efforts to improve the MIPS program through MVPs, the Agency must be cognizant of the resources and time physicians have invested in the MIPS program. Many have significantly shifted their practice to comply with the numerous regulations at a terrible financial toll without benefit to the patient. The MVP framework must not require physicians to make any more changes and should not be mandatory. As CMS moves toward implementation, we urge you to ensure that the MVP framework seamlessly aligns with current practices. CMS is well aware of the paperwork requirements physicians face, and we hope the Agency will not implement the MVP framework in a way that would further increase burden for physicians and other providers. We therefore support a gradual and thoughtful transition to MVPs that would not place any additional burden on providers.

MIPS Performance Category: Telehealth Cost

CMS is proposing to add costs associated with telehealth services to the cost performance category. Specifically, the newly added codes for the COVID-19 pandemic would be added to the costs measures to reflect changes in practice patterns.

ACOFPP appreciates the rationale for this proposal considering the increased utilization of telehealth during the COVID-19 pandemic. As mentioned above, telehealth utilization among physicians dramatically spiked during the first few months of the pandemic. However, we are concerned that the interaction of telehealth costs and potential impact on MIPS scores may not be fully representative of the reality physicians faced during the COVID-19 PHE. Physicians were forced to quickly adapt their practice to telehealth, which required time and resources. Further, adapting to changes in real-time has created some confusion and inefficiencies not present in the normal course of care delivery.

We encourage CMS to consider protections and flexibilities within the operation of the Cost Performance Category, especially as CMS proposes to increase the weight of this performance category. In particular, we urge you to ensure fairness in the cost attribution as some physicians may be inappropriately allocated costs that may or may not be related to the telehealth visit. Additionally, CMS must cognizant that many of the requirements for MIPS and other programs are not possible without a face-to-face visit.

Primary Care Definition for CAHPS Survey

CMS is proposing to codify the primary care definition to include communications technology-based services (CTBS) and telephone E/M services for purposes of assigning beneficiaries to a clinician for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey. In effect, this policy would allow beneficiaries that receive CTBS and telephone E/M services to participate in the CAHPS for MIPS survey for the applicable clinician.

We support this proposal but ask CMS to monitor for any potential program integrity issues. Since CTBS and telehealth are growing in use it is important that physicians are not utilizing this technology in a way that could skew survey results. For example, a provider may unscrupulously use CTBS to expand his or her survey population or to target specific types of patients. We are not suggesting CMS promulgate any additional oversight for physicians, but instead, CMS should monitor CAHPS for MIPS Surveys to ensure its results adequately capture patient satisfaction. We also note that satisfaction scores can be negatively impacted by a patient's unfamiliarity or inability to use technology properly.

MIPS Complex Patient Bonus

CMS is proposing to double the complex patient bonus from 5 up to 10 bonus points for the 2022 payment year (2020 performance year).

ACOFP supports accounting for the direct and indirect effects of the COVID-19 pandemic that may not be accounted for in the 2022 payment year. This proposal is intended to account for complex patients and the overall health impacts from the COVID-19 PHE. We are concerned, however, that this bonus may favor non-family medicine physicians who treat patients with serious complications, skewing bonus points and ultimately MIPS payments away from family medicine physicians.

With reduced in-person visits and delayed care, many patients who would normally count toward family medicine physician complex patient bonus points may instead have gone directly to other specialists, instead of obtaining the critical chronic condition management and preventive services that family medicine physicians provide. We urge CMS to recognize and adjust down quality parameters in response to this phenomenon that skews away from family medicine physicians may result in a further shift of MIPS performance scores (and subsequently payment) to other specialties at the expense of family medicine.