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October 5, 2020

Administrator Seema Verma
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: File code CMS-1734-P; Proposed Rule for CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies (85 FR 50074)

Dear Administrator Verma:

On behalf of the American College of Medical Genetics and Genomics (ACMG), we appreciate the opportunity to comment on the proposed rule for CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies (85 FR 50074; file code CMS-1734-P).

ACMG is the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics, and the only medical specialty society in the US that represents the full spectrum of medical genetics disciplines in a single organization. ACMG is the largest membership organization specifically for medical geneticists, providing education, resources, and a voice for more than 2,400 clinical and laboratory geneticists, genetic counselors, and other healthcare professionals, nearly 80% of whom are board-certified in the medical genetics specialties. ACMG's mission is to improve health through the clinical and laboratory practice of medical genetics as well as through advocacy, education and clinical research, and to guide the safe and effective integration of genetics and genomics into all of medicine and healthcare, resulting in improved personal and public health.

I. Telehealth and Other Services Involving Communications Technology (section II.D.)

In response to the public health emergency (PHE) for the COVID-19 pandemic, the Centers for Medicare & Medicaid Services (CMS) temporarily waived a number of restrictions and expanded access to telehealth services for Medicare beneficiaries. Telehealth is a way to increase access to healthcare for patients throughout the country and potentially reduce health disparities caused by a number of barriers that impede patient access to healthcare providers. The COVID-19 pandemic demonstrated the importance of telehealth as suddenly all patients were faced with a

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severe barrier to access. However, an end to the pandemic will not remove other existing barriers that certain patients already faced. For example, low-income families who do not have adequate transportation or those who cannot afford to take time off from work to travel long distances to and from an appointment would be disproportionately disadvantaged if geographic/originating site and technology barriers remain or if new patients cannot utilize telehealth services where appropriate. This is especially true for services provided by specialists belonging to a small workforce such as medical genetics. For some patients, the closest medical geneticist may be hundreds of miles away, but telehealth expansions can ensure that all patients have access to these specialists regardless of where they live.

For these reasons and more, every effort should be made to ensure that patients continue to have access to appropriate telehealth services. This includes making permanent, where possible, many of the telehealth flexibilities permitted during the PHE and seeking authority to remove barriers to access based on geography and site of service. Further, we recommend that the waivers put in place during the PHE be extended for a period of time after the coronavirus is no longer a threat, such as at least one calendar year after the PHE ends. This will ensure that patients have continued access to care as physicians and care plans adjust to post-PHE practices.

In response to the PHE, CMS added many services to the Medicare Telehealth Services List on an interim basis. In this proposed rule, CMS has proposed to add nine of these services on a permanent basis, and we appreciate that CMS plans to add these services. However, seventy-four others are scheduled to end once the PHE is over. The ACMG provides the following comments about aspects of those other telehealth services.

CMS has proposed to permanently add two codes for home visits for established patients (99347-99348) to the Medicare Telehealth Services List. However, it proposes to cover two other higher-level home visit codes (99349-99350) for established patients on a temporary basis as Category 3 services. We recommend that these higher-level home visit codes (99349, 99350) be made permanent. It can be difficult to anticipate the complexity of these visits until the visit has been completed. For example, patients being assessed for genetic conditions often require more time in education and counseling for rare conditions with which majority of people are not familiar. A complex session requiring more than 25 minutes places the provider in a dilemma to either inappropriately undercode for 99348 or bill either 99349 or 99350 and not be compensated at all.

Additionally, more information is needed regarding the potential value of telehealth coverage of home visits for new patients (CPT 99341- 99345) beyond the PHE.

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CMS recognized the importance of maintaining telehealth access to home visits for new patients during the PHE, and there are numerous barriers to in-person visits that existed prior to the pandemic and will continue to persist after the coronavirus is no longer a threat. We encourage CMS to add these services as category 3 services and collect more information about their value during the PHE. However, we also urge CMS to make category 3 a permanent category that could allow for real-world assessments of promising new approaches before they are authorized for permanent use.

As noted in the proposed rule, the patient home has historically not been a permissible telehealth originating site, but an exception can be made for treatment of a substance use disorder or co-occurring mental health disorder due to authorities included in the SUPPORT for Patients and Communities Act passed in 2018. While outside of the authority of CMS, we believe that the geographic restrictions in section 1834(m)(4)(C) of the Social Security Act should be removed in general. The burden of these geographic restrictions was recognized by CMS during the PHE, and we applaud CMS for using their PHE waiver authority to waive these restrictions where possible. However, the need to deliver telehealth services to patients wherever they are located, including in their own homes, existed before the pandemic and will continue after the pandemic ends. There are a number of situations that make travel to a clinic challenging for a patient regardless of whether they live in a rural or metropolitan area, and these issues are not confined to the COVID-19 pandemic.

In response to the PHE, CMS also used their waiver authority to allow certain telehealth services to be furnished via audio-only communication technology. This waiver should be made permanent for services where possible, and for those services for which legislation is required to make this possible, Congress must take appropriate action. This is especially critical for certain populations who may not have access to computers, smart phones, or other video-capable communication devices or are uncomfortable navigating such technologies. These limitations are most frequently seen in low income or elderly populations, and restricting their access to telehealth services only exacerbates health disparities. The option to use audio-only communication technology should be available as a covered service, in place of a face-to-face visit, when clinically appropriate as determined by the healthcare provider. Further, the current pandemic has highlighted how audio-only communication can enhance the care of patients by providing a medium through which providers and patients can communicate in a timely and effective manner to positively impact patient care.

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For the duration of the PHE, CMS revised the definition of direct supervision to allow for virtual supervision by the supervising physician or practitioner using interactive audio/video real-time communication technology. However, in the proposed rule CMS states that they intend to extend this policy until the later of the end of the calendar year in which the PHE ends or December 31, 2021. CMS also notes that they are concerned that direct supervision through virtual presence may not be sufficient to support PFS payment on a permanent basis due to issues of patient safety. ACMG supports continuation of the current policy through the end of the calendar year in which the PHE ends but recommends that this policy be made permanent. While the examples provided by CMS describing scenarios in which virtual supervision would be insufficient are certainly valid, there are other scenarios where virtual supervision would be perfectly acceptable, such as during most outpatient visits where virtual supervision is arguably quite safe. The fact that remote supervision is inappropriate in some cases does not justify refusing to pay for it under any circumstance. The physician's professional judgment should be relied upon to determine how to appropriately provide supervision in different scenarios.

II. **Scope of Practice and Related Issues (section II.G.)**

In response to the PHE, CMS released an interim final policy allowing supervision of diagnostic tests to be performed by Nurse Practitioners, Clinical Nurse Specialists, Physician Assistants, and Certified Nurse-Midwives as allowed by state laws. ACMG recently joined over 100 other medical specialty organizations and state medical associations in opposing CMS's PHE waivers that expanded scope of practice for non-physician providers (NPPs) and stated our continued support for physician-led health care teams, with each member drawing on his or her specific strengths, working together, and sharing decisions and information for the benefit of the patient.

With regard to the supervision of personnel performing diagnostic tests, it is essential that this medical role continue to be limited to physicians. Requirements for supervision by physicians were put in place to ease concerns about diagnostic tests being performed by NPPs with insufficient training. Eliminating this requirement would remove safeguards that are important to protect patients. While there may be limited scenarios in which a specific NPP has the training adequate to perform a certain test or group of tests, this exception should not be applied broadly. Instead, efforts should be focused on encouraging physician-led team-based approaches that permit physicians the flexibility to safely optimize patient care.

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III. Proposal to Remove Selected National Coverage Determinations (section III.J.)

CMS has proposed to remove NCD 190.3, Cytogenetic Studies, based on the inaccurate rationale that genetic sequencing is now more common than cytogenetic studies. While there has been a shift to molecular cytogenetics, cytogenetic studies have not been replaced by genetic sequencing. Cytogenetic studies are commonly used and are especially important in cancer diagnoses as well as numerous other conditions, and multiple professional guidelines and practice resources exist that support use of cytogenetic studies. While cytogenetic studies are still very relevant and should remain nationally covered, the terminology in NCD 190.3 is very outdated. ACMG encourages CMS to refine the language to reflect modern terminology and advances in our understanding of genetic and genomic conditions, and we remain available to assist CMS to ensure that language is appropriate.

IV. Regulatory Impact Analysis (section VIII.)

ACMG supports CMS's decision in last year's Medicare physician payment final rule to utilize the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel coding framework and AMA Specialty Society Relative Value Scale Update Committee (RUC) recommended values for office and outpatient visits starting January 1, 2021. The new policy will reduce administrative burden and better reflect the resources involved in office visits. Additionally, we understand that CMS is required by law to implement budget neutrality adjustments, and the CY 2021 Medicare PFS conversion factor is proposed by CMS to be $32.26. This drastic reduction, an almost 11% reduction from CY 2020, is extremely concerning, especially given the financial instability for physician practices that has been created by the current pandemic. We have previously joined numerous state and specialty medical societies in urging HHS to utilize its authority under the public health emergency declaration to preserve patient access to care and mitigate financial distress due to the pandemic by implementing the office visit increases as planned while waiving budget neutrality requirements for the new Medicare office visit payment policy. We reiterate that here and urge CMS to work with HHS to identify ways to mitigate the financial impact while the public health emergency persists and lessen the impact of the conversion factor.

V. Conclusions

By rapidly adapting to the COVID-19 PHE and reducing restrictions on virtual healthcare, CMS helped millions of Americans maintain access to vital services. As a result, CMS protected Americans, reduced unnecessary exposures, and saved

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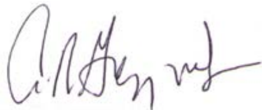
lives. However, there are numerous other barriers in access to healthcare that existed prior to the pandemic and will continue to persist after the PHE ends, and many of these barriers lead to or exacerbate health disparities. We appreciate the steps that CMS has taken to improve access to healthcare through telehealth services and encourage CMS to make more of these services permanent beyond the end of the PHE so that all patients have continued access to healthcare.

Sincerely,



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