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September 13, 2021

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The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
Mail Stop C4-26-05
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Baltimore, MD 21244-1850

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Re: File Code CMS-1751-P; Medicare Program; CY 2022 Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (July 23, 2021)

Dear Administrator Brooks-LaSure:

Eric M. Plakun, M.D.
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The American Psychiatric Association (APA), the national medical specialty society representing over 37,400 psychiatric physicians who treat mental health and substance use disorders (MH/SUD), would like to take the opportunity to comment on the proposed rule on the 2021 Medicare Physician Fee Schedule and Quality Payment Program. Our comments focus specifically on issues that affect the care of patients with mental health and substance use disorders (MH/SUDs).

**Assembly
2021-2022**

Mary Jo Fitz-Gerald, M.D., M.B.A.
Speaker

Adam Nelson, M.D.
Speaker-Elect

Vasilis K. Pozios, M.D.
Recorder

As has been widely reported, the COVID-19 pandemic has further exacerbated mental health conditions, including substance use disorders. Earlier this year, the Centers for Disease Control and Prevention reported a record-breaking 81,230 drug overdoses during the previous 12-month period ending in May 2020. This represents an eighteen percent increase in drug overdose deaths over the previous 12-month period. Last month, the Kaiser Family Foundation reported that during the pandemic, about four in ten adults in the United States have reported experiencing anxiety or depression -- an increase from one in ten individuals during the previous year. Suicide is the 10th leading cause of death. In 2019, 12 million Americans had serious thoughts of suicide and 1.379 million Americans attempted suicide. Despite progress in the distribution of COVID-19 vaccines and the inoculation of increasing number of individuals, social isolation and the economic repercussions caused by the pandemic will continue to compound the mental health challenges for individuals across the country making access to care a critical component of the Nation's recovery.

Administration

Saul Levin, M.D., M.P.A.
CEO and Medical Director

There are a number of provisions in the proposed rule that will have a direct impact on access to care psychiatric care. Thank you for the opportunity to comment.

CALENDAR YEAR 2022 UPDATES FROM THE PHYSICIAN FEE SCHEDULE (PFS)

APA urges CMS and HHS to work together with Congress to waive the budget neutrality adjustment set to go into place for 2022. The 3.75% reduction in the Medicare conversion factor will have a significant financial impact on psychiatrists who treat Medicare patients and comes at a time when practices have already experienced financial losses due to the PHE. Payment cuts will only further compound the growing access problem for patients with mental health and/or substance use disorders.

Determination of Practice Expense (PE) Relative Value Units (RVUs) (Section I.A)

Changes to Direct PE Inputs for Specific Services

Technical Corrections to Direct PE Input Database and Supporting Files

We thank CMS for quickly responding to our request to restore the payment levels for services related to self-administered esketamine to their 2020 amounts. As we have noted in previous letters, finalizing payments that are insufficiently valued will impede access to this medically necessary treatment. We acknowledge the challenges of valuing this service using the existing payment methodology and encourage CMS to sustain the current rates to ensure payment stability. The vast majority of services are provided by psychiatrists and our members report that adding this treatment modality to their practices has resulted in increased costs such as: 1) administrative support to order and coordinate receipt and complete the required documentation for the REMS process, 2) handling of secure storage and disposal of a controlled substance, and 3) additional office space to accommodate this activity. These indirect costs, which are not insignificant, are above and beyond that of a typical psychiatric practice. **We strongly encourage CMS to maintain the current rates to ensure beneficiary access to this evidence-based treatment option.**

Clinical Labor Pricing Update

APA appreciates CMS' decision to update the clinical labor pricing to reflect current labor costs more accurately and supports implementing the changes over a four-year period. However, we are concerned about the impact this change will have on payments under the physician fee schedule when the budget neutrality adjustment is applied. We are especially concerned about the negative impact a 17% reduction (for 2022) in practice expense RVUs for 99493, subsequent psychiatric collaborative care (CoCM) services, will have on the uptake and continued use of the collaborative care model. This reduction is not insignificant for those primary care practices that have implemented this evidence-based model of care, particularly considering the frequency with which this code is billed. We want to continue to encourage primary care practices to adopt the collaborative care model which has been shown to increase access to effective care and reduce overall healthcare costs. With the significant increase in need for services, now is not the time to create barriers that impact access to treatment for mental health and substance use disorders. **We strongly encourage CMS to update the clinical labor**

inputs on a more frequent basis to mitigate the impact the changes have on the overall fee schedule pricing. And we urge CMS to call on Congress to provide a positive update to the Medicare conversion factor for 2022 and all subsequent years to mitigate the negative impact of these changes.

Potentially Misvalued Services Under the PFS (section II.C.)

Principal Care Management and Chronic Care Management (CPT Codes 99490, 99439, 99491, 99X21, 99487, 99489, 99X22, 99X23, 99X24, and 99X25)

We appreciate CMS' ongoing support and recognition of the importance of care management services such as principal care management, chronic care management and psychiatric collaborative care management (CoCM) services, all of which require beneficiary consent. **We support the need for beneficiary consent and recommend that CMS allow clinical staff to obtain consent under general supervision of the treating physician. We also urge CMS to implement this flexibility across all care management services including the psychiatric collaborative care management services. Given the increasing number of care management services we recommend that CMS ensure consistency in coverage policies across services and sites of service.**

Telehealth and Other Services Involving Communications Technology, and Interim Final Rule With Comment Period for Coding and Payment of Virtual Check-In Services—Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (section II.D)

Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA), Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology

Over the course of the pandemic, clinicians and patients across the country transitioned seemingly overnight to the use of telehealth. This was especially true for APA member psychiatrists as revealed by [two APA surveys](#) that highlight the rapid switch to virtual care. CMS moved quickly to accommodate the need for physical distancing by expanding covered telehealth services for beneficiaries by temporarily waiving the originating site and geographic location requirements for beneficiary eligibility; allowing for the provision of telehealth services via audio-only (telephonic) interaction between eligible clinicians and patients; and allowing for the supervision of physician residents via telemedicine. All of these changes ensured access to care during a time when in-person treatment carried significant risks and the need for mental health and substance use treatment increased. The changes also showed the potential and benefits of virtual care in meeting treatment needs, including reduced no-show rates for appointments increasing continuity of care and increased patient satisfaction.

APA appreciates many of CMS' proposals in this NPRM that would either make permanent—or otherwise continue to temporarily extend and evaluate—many of the telehealth provisions that clinicians and patients have relied on over the course of the public health emergency (PHE), which have improved access to care. For example, allowing for certain services to remain on CMS' eligible telehealth code list through December 31, 2023 will: a) ensure continuity of care for many patients and b) allow for CMS to collect pertinent use data on these services to assess uptake and access to mental health care via telehealth.

However, we urge consideration of the following recommendations to ensure patients continue to access care as needed:

APA supports CMS' proposal to amend the current regulatory requirement for interactive telecommunications systems to include audio-only communication technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients in any location. APA strongly recommends expanding this coverage to include new patients with mental health disorders as well as new or established patients with substance use disorders.

Overall—in addition to our specific comments below—APA **recommends that CMS maintain the current audio-only flexibilities that have been in place from early on in the public health emergency permanently or left in place through at least December 31, 2023.** Continuing to provide necessary care to patients with mental health or substance use disorders, including MAT, via audio-only care ensures there is a way for any individual to access care. Should CMS decide not to extend coverage for patients with substance use disorders we ask CMS to provide the rationale and clarify any limitations (regulatory or other) for that decision.

APA is concerned about any requirement for a patient to be seen in-person by a practitioner in order to be eligible for any telehealth encounter, regardless of whether the telehealth encounter is conducted via synchronous video or via audio-only. Requiring an initial or subsequent in-person visit for a patient to qualify for a telehealth encounter of any modality will be a barrier to care. Presently, there does not appear to be concrete evidence as to the value or necessity of requiring an in-person visit prior to engaging in telemental health care. In fact, emerging evidence suggests that implementing requirements such as these may possibly dilute the benefits of easily accessed telehealth, including audio-only care.

Indeed, some research suggests that limiting access to audio-only care may increase disparities among certain populations. For example, a survey conducted by The California Healthcare Foundations¹ revealed that more than a third of respondents (38%) had received a phone visit, and 72% said they were just as, or more, satisfied with their phone visit compared to their last in-person visit, and that high utilization of, and satisfaction with, phone visits specifically among those with low incomes and among people of color, who already face significant barriers to traditional and telehealth care.

Moreover, Medicare beneficiaries in particular are more likely to be negatively impacted by such requirements, especially as it applies to audio-only care. Putting restrictions on audio-only care will disproportionately affect the poor, elderly, and those living in areas that lack transportation or access to broadband and who already face other (i.e., technological) barriers to accessing care.

¹ "The Doctor Will Call Me Maybe: The Uncertain Future Of Audio-Only Visits And Why We Need Them To Address Disparities, " Health Affairs Blog, March 3, 2021.DOI: 10.1377/hblog20210225.26462

Specifically, patients who cannot interact with their physician via a live, synchronous audio-video connection may need to rely on audio-only care for myriad reasons: they may lack access to sufficient broadband internet or access the technology itself (e.g., they may not own a smartphone, tablet, or PC); their diagnosis may preclude using such technology; or they may not consent to being seen via video. There is even a notable percentage of telehealth visits that fail, resulting in an audio-only visit. We want to ensure that all individuals have equitable access to evidence-based care regardless of their personal circumstances and in lieu of no care at all.

APA therefore strongly encourages CMS to allow for flexibility in cases where an audio-only format might be the only way for beneficiaries to access a clinician. The proposed 6-month timeframe is arbitrary and the decision to recommend an in-person visit should be at the discretion of the clinician, based on the patient's medical/therapeutic needs or when other (e.g., travel time/distance of the patient to the provider's office) circumstances warrant it. **We also recommend CMS remain silent with regard to the provisions incorporated in the Consolidated Appropriations Act (CAA) that require an in-person visit for all new patients until there is evidence to suggest an in-person visit is necessary.**

APA supports CMS' proposal to limit the use of audio-only mental health and substance use care to clinicians who have the capability to use synchronous, live videoconferencing but where the patient is not capable of using or does not consent to using it. We also support the adoption of a modifier that identifies the service was provided via audio alone. With respect to CMS' request regarding more information on whether additional documentation should be required in the patient's medical record to support the clinical appropriateness of audio-only telehealth, **APA recommends that a simple indication in the clinical progress note related to the patient's condition and the provision of audio-only care be sufficient.**

As for the types of services that can be performed via audio-only, most evidence-based treatments for mental health and substance use disorders can be provided, when necessary and at the clinician's discretion, via an audio-only modality. Ultimately the clinician should be making the decision as to the clinical appropriateness of the modality of care. Psychotherapy, evaluation and management services, including high level E/M services, and psychotherapy for crisis, can all be done by audio-only alone. A high-risk patient with suicidal thoughts and behaviors can be effectively managed by audio-alone when determined to be appropriate by the clinician. **APA recommends CMS expand the current telehealth list of audio-only covered services to include all of the outpatient evaluation and management services (99202-99215).** Clinicians should use the same CPT codes for audio-only care as they would if they saw the patient via telehealth or in-person. The service would be differentiated only by use of a modifier as proposed by CMS. Payment rates for audio-only care should be no less than the established rates for in-person or care provided via telehealth, as the time and nature of the work, and the expenses for the treating clinician remain the same regardless of the treatment modality.

We appreciate that CMS is concerned as to whether an encounter completed via audio-only telehealth may possibly preclude the patient receiving the total benefit encapsulated within the telehealth codes. APA acknowledges that the evidence for audio-only telehealth treatment in the long-term is still emerging and encourages CMS to use the proposed audio-only modifier in conjunction with other outcomes

measures to evaluate both uptake and outcomes in order to inform future rulemaking. Use of techniques such as measurement-based care - monitoring progress through the use of validated rating scales – when implemented appropriately and without burdens that negatively impact the clinical interaction, has been shown to support clinical care and improve patient outcomes and can be done regardless of the mode of interaction (in-person, telehealth or audio-only) with a patient.²³

Lastly, CMS has expressed concerns about the increased utilization and risk for fraud and abuse. As with any medical service provided in-person or via telehealth, CMS already has robust mechanisms in place to identify potential fraudulent activity.

Payment for the Services of Teaching Physicians (section II.G.)

The APA applauds the decision to allow teaching physicians to use audio/video real-time communications technology to supervise residents during the pandemic and include the total time considered for visit level selection. The current flexibilities due to the COVID-19 PHE allow teaching physicians to supervise residents, either in-person or virtually through audio/video real-time communications technology, during the key portion of services including psychiatric services. These expansions of supervision have been successful during the COVID-19 PHE and **APA recommends the permanently maintaining the ability for all teaching physicians to supervise residents via audio/video real-time communications technology.**

These supervision expansions must be made in accordance with Accreditation Council for Graduate Medical Education (ACGME) policy, taking into account program, specialty, patient, and trainee factors, will enable residents to provide additional services while still garnering the oversight needed from their teaching physicians. Decisions regarding how residents will be supervised via audio/visual real-time communication technology should be implemented, reviewed, and overseen at the program level, in accordance with ACGME policy. Decisions about appropriate supervision and the type of technology used must be appropriate for the clinical setting and the needs of the individual patient, as well as the health and safety of the residents, fellows, and teaching physicians involved. We acknowledge that in some situations it will be appropriate for a resident/fellow to conduct a patient encounter remotely and then discuss the case with the supervising teaching physician using audio/visual communications. In other situations, the resident/fellow and supervising teaching physician should both physically participate in the patient encounter as determined by the individual program and ACGME. This addition of audio/visual supervision does not change the responsibility of the institutions' GME Committees, which must still monitor programs' supervision of residents and ensure that supervision is consistent with the provision of safe and effective patient care, the educational needs of residents, the progressive responsibility appropriate to residents' levels of education, competence, and experience, and any other applicable common and specialty/subspecialty specific program requirements.

² Fortney JC, Unützer J, Wrenn G, Pyne JM, Smith GR, Schoenbaum M, Harbin HT. A Tipping Point for Measurement-Based Care. *Focus (Am Psychiatr Publ)*. 2018 Jul;16(3):341-350. doi: 10.1176/appi.focus.16303. Epub 2018 Jul 16. PMID: 32015714; PMCID: PMC6996080.

³ Alter, C.L., Mathias, A., Zahniser, J., Shah, S., Schoenbaum, M., Harbin, H.T., McLaughlin, R, & Sieger-Walls, J. *Measurement-Based Care in the Treatment of Mental Health and Substance Use Disorders*. (2021, February). Dallas, TX: Meadows Mental Health Policy Institute. mmhpi.org.

Currently, payment for teaching physician services will be made when the teaching physician renders sufficient personal and identifiable physician's services to the patient including exercising full, personal control over the management of the portion of the case for which payment is sought. In the case of E/M services, the teaching physician must be present during the portion of the service that determines the level of service billed. The PFS is proposing that when total time is used to determine the office/ outpatient E/M visit level, only the time that the teaching physician was present can be included since the Medicare program makes separate payment for the program's share of the resident's graduate medical training program, which includes time spent by a resident furnishing services with a teaching physician, under Medicare Part A. **The APA supports this proposal and believes that adequate payment will still be provided for teaching physician services.**

Billing for Physician Assistant Services (section II.G.)

Every member of the care team plays an important role and patients benefit when every member of the team, including physician assistants (PAs) and physicians work together sharing information, and their unique skills toward high quality patient care. They are often the first and last person to interact with a patient during an episode of care and are well-equipped to play advanced roles in the health care team. However, PAs are no substitute for physicians in diagnosing complex medical conditions, developing treatment plans that take into account patients' wishes and limited health care resources, and ensuring the treatment plan is followed by all members of the health care team.

Every team needs a leader and physicians bring with them the highest level of education and training, making them uniquely qualified to lead the health care team. Every state in the country requires PAs to practice with some level of physician involvement. It is imperative, therefore, that any changes to the billing authority of PA's as proposed in the PFS does so within the parameters of these state laws and ensures such billing authority does not negatively impact the quality of patient care. To date, PA services have been covered under Medicare Part B only when billed by the PA's employer, with a few narrow exceptions. Medicare Part B payment could be made to the qualified employer of a PA and the PA could furnish services under a W-2 employment relationship, an employer-employee relationship, or as an independent contractor through a 1099 employment relationship. The regulation also specified that a group of PAs that incorporated to bill for their services were not a qualified employer. However, section 403 of the Consolidated Appropriations Act, 2021 removed the requirement to make payment for PA services only to the employer of a PA effective January 1, 2022.

The PFS is looking to implement the change from the Consolidated Appropriations Act, 2021 which will allow PAs to bill the Medicare program, be paid directly for their services, reassign their rights to payment for their services, and incorporate as a group comprised solely of practitioners in their specialty and bill Medicare. This change will impact only the statutory billing construct for PA services. It did not change the statutory benefit category for PA services, including the requirement that PA services are performed under physician supervision or collaboration and in accordance with state scope of practice laws, nor did it change the statutory payment percentage applicable to PA services.

More than half of patients with mental illness and substance use disorders also have an underlying physical illness. For example, people with diabetes or heart disease often suffer from depression. The complex interactions between mental and physical health conditions and the medications used to treat them require advanced medical training in order to ensure high-quality clinical care through adherence to best practices, which typically leads to highly positive health outcomes. We know that mental health and substance use related conditions can compromise outcomes and drive costs of medical care. Efforts at integrated care models are increasing, with funding streams being designed to help improve quality while containing costs. These models depend on thoughtful clinical judgment and proper management of complex conditions. A physician who provides oversight or collaborative consultation, with comprehensive knowledge of clinical needs, is essential to achieve these aims.

As such, PAs should be authorized to provide patient care services only so long as the PA is functioning under the direction and supervision of a physician or group of physicians. The training PAs receive does not substitute for the comprehensive knowledge and skills physicians acquire as a function of their medical school education and experience. The key difference between medical and physician assistant education and training is the fact that medical students spend four years focusing on the entire human body and all of its systems—organ, endocrine, biomedical, neuropsychiatric, and more—before undertaking three to seven years of residency training to further develop and refine their ability to safely evaluate, diagnose, treat, and manage a patient’s full range of medical conditions and needs. By gradually allowing residents to practice those skills with greater independence, residency training prepares physicians for the independent practice of medicine. Combined, the most basic medical school and residency training total more than 10,000 hours of clinical education and supervised training experience, including basic course work as well as years of practical supervised experience with patients. The very nature of physician assistant training involves working with physicians; physician assistants are not trained to provide patient care without physician supervision. Even physicians do not work independently before the end of their residency, even though at that point they have much more education and training than physician assistants. Physician assistants just do not have extensive training in pharmacology, differential diagnoses, or the years of education and training regarding the human body and its systems that physicians have.

The vast majority of states’ regulations reflect the necessity for oversight of PAs and the importance of physician-led care. In 48 states a PA’s scope of practice is determined with the supervising or collaborating physician at the practice site. Moreover, in 34 states PAs are supervised by physicians and in 16 other states PAs are subject to other forms of collaborative or alternative agreements. Thus, as the billing abilities of PAs change it is important to ensure that this change does not impact the care the patients receive or the scope of practice requirements that are in place.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (sections III.A., III.B., and III.C.)

APA fully supports CMS’ proposal to allow RHCs, FQHCs, and Critical Access Hospitals to provide audio-only services, in a patient centered-manner and based on the clinical judgement of the clinician. As we stated previously with regard to expanded telehealth services, **APA is concerned about any requirement**

for a patient to be seen in-person by a practitioner in order to be eligible for any telehealth encounter. Again, implementing requirements such as this may dilute the benefits of the expanded policy. We also encourage CMS to expand audio-only coverage to include treating patients with substance use disorders. We support RHCs and FQHCs receiving their usual PPS or AIR rates for audio-only telehealth services and support the billing for both G0511 and G0512 in the same month for the same patient as long as the time and effort is not counted more than once.

Medicare Shared Savings Program (section III.J)

APA is supportive of the Medicare Shared Savings Program and the Accountable Care Organization concept; facilitating better coordination and integration of care is critical to improving the quality of mental and behavioral health care, and the Shared Savings program is an important step in promoting these goals. However, we are concerned that some of CMS's proposed policies may undermine the ability of ACOs to meet requirements under the program. Electronic clinical quality measures are important for reducing data collection burdens and incorporating clinically-enriched data into measurement activities, but a continued lack of EHR standardization raises concerns about the feasibility of aggregating data from diverse and disparate systems that may be in use across an ACO. Furthermore, the practice of introducing new measures on a 'pay-for-reporting' basis before incorporating them into payment calculations is an important step in the process of building a valid and feasible measure set, allowing participants to identify potential problems or unintended consequences that may arise with measure implementation. We would encourage CMS to continue consulting with the ACO and clinician communities and patient representatives to determine the best-balanced measure set and measurement approach for the Medicare Shared Savings Program.

APA also supports the inclusion of the Behavioral Health Integration codes (99492-99494, G2214, and 99484) in the definition of primary care services for the Shared Savings Program.

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.O.)

We appreciate the two proposed changes included in this section to improve access to care for patients with opioid use disorder by allowing payment for a recently FDA-approved higher dose of naloxone hydrochloride nasal spray product to treat opioid overdose.

We also support allowing the therapy and counseling portions of the weekly bundles, and any additional counseling or therapy provided by opioid treatment programs, to be furnished using audio-only telephone calls rather than via two-way interactive audio/ video communication technology for the duration of the PHE for COVID-19. This is important given many patients do not have smart phones that allow for two-way communication.

Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan (section 2003 of the SUPPORT Act) (section III.Q)

APA appreciates CMS' continued flexibility around the compliance date requiring the electronic prescription of controlled substances (ECPS) for Part D clinicians in light of the PHE. As noted in this

proposed rule, and in APA's previous letters to the Administration, the PHE resulted in numerous practical and administrative constraints of physicians in transitioning to ECPS by the original date of January 2021, and we appreciate CMS' previous action in moving the compliance date to January 2022. **APA supports CMS' current proposal to move compliance to January 2023.**

APA also supports the proposed compliance threshold that would apply to all ECPS for Part D clinicians, including:

When it would be impractical for the patient to obtain medication(s) prescribed by electronic prescription in a timely manner and such delay would adversely impact the patient's medical condition

When the National Council for Prescription Drug Programs (NCPDP) standard does not support transmitting the prescription

APA also recommends that CMS consider an additional compliance threshold based on clinician practice size, such as used in the MIPS Promoting Interoperability program.

Updates to the Quality Payment Program (section IV.)

APA appreciates CMS's effort to make minimal changes to the QPP program in light of the COVID-19 Public Health Emergency and the unique pressures our health care system continues to be under at this time. Our comments focus on the MIPS Value Pathways (MVPs) program and efforts to incorporate cost measures into the MIPS program.

Cost measures

APA continues to have strong concerns about application of episode-based cost measures (ECBMs) to individual clinicians, both as part of the overall MIPS program and through MVPs specifically. As APA has expressed previously, existing and proposed ECBMs, as applied to psychiatrists, present serious challenges across multiple dimensions, including but not limited to:

Psychiatrist control over key cost-related factors

There is a limited range of costs that are directly within the control of individual psychiatrists, particularly those practicing in the inpatient environment, and minimal opportunities to exert indirect control over many of the costs included as part of the current ECBM attribution methodology. This undermines both the validity of the measures and their effectiveness of measures as incentives for behavioral change, as clinicians will find it difficult to understand how their behavior is connected to increases or decreases in cost measure scores.

Potential for unintended consequences

Without a full understanding of contributors to the varying costs of psychosis related care, emphasizing cost reduction creates a significant likelihood of unintended consequences, including potential for the measure to exacerbate problems with access to care. Many psychiatrists care for a highly vulnerable population of patients who experience high rates of unemployment ~~high~~ and where socioeconomic challenges are common. We know that individuals with serious mental illness have substantial physical health comorbidities and a lifespan that is as much as 20 years less than that of the population as a

whole. Cognitive aspects of aging also appear to be accelerated in these individuals. Efforts to reduce costs of care in these individuals may place them at even further disadvantage, with even greater disparities among Blacks, Latinx, and Indigenous People as has been starkly evident in health care delivery during the pandemic. **We urge CMS to avoid implementing measures or policies that have the potential to deepen inequities in access to care.**

Transforming MIPS: MIPS Value Pathways

APA supports the concept of MVPs and applauds CMS's efforts to develop a measurement program that is more conceptually coherent, focused on improvement, and relevant to specialty practices than past activities. However, as expressed above, there remain serious practical concerns about the implementation of cost measures, which are a key component of MVPs. We are concerned that use of problematic cost measures will undermine the intent and effectiveness of the MVP program, and could lead to unintended consequences, such as 'cherry-picking' of patients who are likely to be lower-cost, or further reduction in the number of psychiatrists willing to accept Medicare patients.

There also continues to be gaps in clinically-relevant quality measures for psychiatrists; we hope and expect that this will be improved over time, but at present, the set of measures available for mental and behavioral health is limited and is focused largely on process metrics that have not been demonstrated to have a high impact on patient outcomes.

CMS requests comment on what should happen when specialty clinicians cannot identify an applicable and relevant MVP. APA would suggest that CMS slow the transition from traditional MIPS to MVPs to accommodate clinicians who cannot identify MVPs that are directly relevant to their clinical practices, allowing those clinicians to continue their participation in traditional MIPS until an appropriate MVP is available.

Other CMS measurement policies

In addition to our comments on the proposed rule, APA would like to note that having a sufficient number of quality measures available for psychiatrists and members of the mental health care team is a priority for APA. We anticipate that this will likely involve developing and then moving QCDR measures through the Measures Under Consideration process and into the MIPS program. Over the course of the last four years, the number of measures approved via the MUC has declined precipitously, from several dozen measures to only four quality measures last year. Combined with measure attrition, the availability of quality measures for groups to report has become much tighter. CMS should rebuild the library of MIPS measures available for reporting by encouraging the submission of QCDR measures through the MUC process. However, rebuilding a library of quality measures will be challenged by regulations finalized by CMS last year. We are very concerned about CMS's policy on measure testing for 2023 and beyond. In the 2021 quality payment program rule, CMS finalized a proposal to require face validity testing for measures in 2022 and then "full testing" for measures submitted as part of the QCDR in 2023. Because data to fully test a quality measure for validity is difficult to capture, we cannot support requirements that each measure be tested for validity beyond face validity.

We recognize that CMS will attempt to implement these testing requirements over the next year. In 2020 and again in 2021, CMS rightly allowed groups that were disrupted by the COVID-19 pandemic to apply for and receive a hardship exemption. That policy, however, reduced the amount of data available for measure testing. Because the extreme and uncontrollable circumstances policy decreased the number of groups able to report quality data, we ask that measure testing requirements (not including face validity testing) be delayed until two years after the end of the public health emergency (PHE).

In addition, CMS should approve an improvement activity for groups that assist measure stewards with measure development and testing efforts. Measure development requires a significant amount of time, money, and analysis to complete, and often relies on volunteers to collect and report data to help assess measure feasibility, reliability, and validity. Offering MIPS eligible clinicians and groups opportunities to earn improvement activities credit for helping improve the measures offered in MIPS is a worthwhile and meaningful action CMS can take immediately.

Proposed Changes to the Medicare Promoting Interoperability Program

The APA appreciates the continued flexibility in reporting requirements under the Promoting Interoperability program for Eligible Clinicians (ECs), including options surrounding measure choice, scoring, and opportunities for bonus points. Please find feedback regarding the proposed changes below:

4(b) ...the performance period for the Promoting Interoperability performance category is a minimum of any continuous 90-day period within CY 2022...we are not proposing any changes to the Promoting Interoperability performance category...

APA appreciates that CMS has maintained the 90-day reporting period for these electronic measures since the inception of MACRA in 2015. **APA supports maintaining this reporting period window, keeping consistent with previous reporting years.**

Proposed Changes to the Query of Prescription Drug Monitoring Program Measure Under the Electronic Prescribing Objective (4 (c)(i))

APA supports maintaining the PDMP measure as optional for CY2022, and also supports increasing the bonus for reporting on this measure from 5 points to 10. As we have stated in previous letters to CMS, it is still premature to require the Query of PDMP measure and then include it in the Promoting Interoperability score. As CMS has acknowledged, there are still technical challenges associated with connecting PDMPs with various EHR systems. Our membership remains affected by these technical challenges, which include: a) a lack of standards connecting PDMPs and EHRs, b) the policy (e.g., statutory) and other technical challenges around integrating state PDMPs with HIEs and hospitals, c) addressing the challenges in integrating PDMP queries seamlessly into physician workflows, d) the cost and time required for developers—and subsequent downstream financial impact on physicians/hospitals—to develop standards and technological solutions to better integrating PDMPs with other health IT software and finally, e) the burden in tracking and calculating numerator/denominator requirements for the PDMPs.

Moreover, not only do these challenges remain, but they were difficult to address during the PHE by healthcare organizations, as they shifted resources to mitigate the ongoing public health crisis. Additionally, as ONC and CMS' Final Rule around Interoperability and Information Blocking were released in 2020, with the revised Applicability Date of April 2021, clinicians' and vendors' priorities had to be adjusted to meet the expectations around complying with these regulations. Thus, waiting to require the Query PDMP measure under the Electronic Prescribing Objective would give hospitals and vendors more time to adapt their systems accordingly.

As the technology necessary to connect PDMPs with HIT systems matures, requiring this measure will become less burdensome. For example, the 2020 PFS outlined a transition to the updated CEHRT 2015 Edition standard and a transition for CEHRT to use the NCPDP SCRIPT 2017071 standard for electronic prescribing; the ONC, in its 21st Century Cures Final Rule, requires those vendors developing CEHRT for Promoting Interoperability will use FHIR open APIs to connect providers and other users of HIT. Given these advancements, APA is optimistic that, in time, the data captured by PDMPs will be able to flow through the HIT ecosystem without significant burden to hospitals and providers. We look forward to continuing to be part of the conversation regarding how the Query PDMP measure can be successfully implemented in the Medicare Promoting Interoperability Programs in the future.

(B) to modify the Provide Patient's Electronic Access to Their Health Information measure to establish a data availability requirement beginning with encounters with a date of service on or after January 1, 2016, beginning with the EHR reporting period in CY 2022

Currently, the Provide Patient Access to Their Health Information does not specify how long MIPS eligible clinicians are required to make patient data available, or to ensure that patient data remain available to patients in the event that an EC switches EHR vendors. APA appreciates CMS' intent to align the Provide Patient Electronic Access to Their Health Information measure with the look-back period finalized in the Patient Access and Interoperability final rule. While the January 1, 2016 date seems reasonable for ECs, **the APA recommends that CMS delay enforcement discretion from July 1, 2021, to the end of CY 2021, to account for the ongoing COVID-19 PHE.**

Moreover, APA seeks clarification that, during this lookback period, and other proposed future accessibility requirements around changes to the Provide Patient Access PI measure, that ECs can exercise the pertinent Exceptions under the Information Blocking and Interoperability Final Rule. Specifically, that the Infeasibility, Content and Manner, and Health IT Performance Exceptions may be employed, when applicable, by the EC, when maintaining patient data in near-perpetuity may not be possible for MIPS-eligible clinicians. Additionally, APA seeks clarification on whether this change to the Provide Patient Access measure will only apply to the reporting years for which the clinician was eligible and did not meet any of the MIPS program exceptions, such as the low-volume threshold.

Clarifying the above points will help to reduce burden among solo and small group psychiatrist ECs who may not participate in MIPS in consecutive years.

Reweighting the Promoting Interoperability Performance Category for MIPS Eligible Clinicians in Small Practices

APA appreciates CMS' continued efforts to reduce administrative and financial reporting burden for small practices endeavoring to participate in MIPS. As noted in this Proposed Rule, many small practices may be eligible for the LVT; or, qualify as small practices (i.e., under 15 ECs), and therefore can apply for an Exception to the Promoting Interoperability category, when there are "overwhelming barriers" to participating.

In response to the questions posed in this Rule, APA is unable to ascertain the specific reason(s) as to why some small practices may fail to apply for the Small Practice Hardship Exception for the Promoting Interoperability performance category, while still participating in MIPS as a whole. This is possibly because many of our members in solo or small group practices qualify for a total exemption for all of MIPS under the Low Volume Threshold; or, as CMS contemplates in this rule, they may be unaware of the Exception itself, or may believe that they do not meet the requirements of "overwhelming barriers."

Regardless of reason, **APA supports CMS' recommendation to automatically redistribute points from the PI performance category to other performance categories of MIPS for small practices who do not apply for the Exception, but who would have been eligible, in order to avoid receiving a score of zero for the PI category.**

(ii) We are proposing to add a new SAFER Guides measure to the Protect Patient Health Information objective...we are proposing that a MIPS eligible clinician must attest to having conducted an annual self assessment using the High Priority Practice Guide, at any point during the calendar year...with one "yes/no" attestation statement accounting for the complete self-assessment using the guide.

Generally, the APA supports the use of the Safety Assurance Factors for EHR Resilience (SAFER) Guides, particularly the High Priority Practices Guide, as a part of the Promoting Interoperability performance category. Requiring ECs to attest to completing these guides has the potential to help many clinicians enhance and optimize health IT, ensuring that they are "responsible operators of technology tools," as stated in this proposed rule. This attestation is reminiscent of the existing Security Risk Assessment measure in its utility to safeguard patient information, and in that it will not be scored for PI. While we appreciate CMS' acknowledgement ECs (especially those in solo or small group practice) vary in terms of resources with respect being able to complete the SAFER attestation annually, APA recommends that, for the 2022 RY, **CMS conduct an audit of those entities that attest "no," in order to ascertain why they did not complete a SAFER attestation, to see if additional resources might support them in doing so for future reporting years.**

(e) We are also more broadly soliciting public comment to help us better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and AI.

In addition to this broader prompt, CMS poses a list of questions for consideration regarding the use of innovative technologies within physician practices. For example, the Rule considers how technologies,

such as AI, have affected physician work time and intensity of furnishing services (e.g., possibly reducing the amount of time that a practitioner spends time reviewing and interpreting results of diagnostic testing), or how technologies are changing cost structures, affecting access to services for Medicare beneficiaries, and more.

While APA and psychiatry continues apace in adopting new technologies into clinical workflows—such as adjunctive therapeutic mobile applications, and wearables—it is qualitatively different from how other specialties are using it. For example, in the Rule, CMS uses examples such as a simulation software analysis of functional data to assess the severity of coronary artery disease and how trabecular bone score software can supplement physician work to predict and detect fracture risk. These examples might be considered as straightforward use cases of emerging technology where an attempt to codify and quantify their value to Medicare practitioners and beneficiaries seems reasonable. For psychiatry some analogous use cases, such as various emerging technologies utilizing focused on discrete physiological symptoms (e.g., neuropsychiatry, movement disorders, clinical decision support, work on neurolinguistics in detecting changes in language use patterns in predicting psychopathy or dementia); however, presently, there are too few datapoints and replicated research into how AI or other technologies are or can affect psychiatric work flows, physician time, and other considerations as contemplated in this Rule.

The use of AI in healthcare is still nascent. With respect to psychiatry, most AI-driven tools are embedded within health IT products more appropriately described as “augmented intelligence” rather than “artificial intelligence.” The scope of this technology tends to encompass features of electronic health records (EHRs), such as electronic clinical decision support (eCDS), and in mHealth, such as apps that rely on patients’ behavioral history to send warnings to the patient about environmental factors that could potentially be triggering for mental health conditions, such as substance use disorders.

While APA is optimistic that the future of AI may improve patient care and lead to better outcomes, we are concerned that there are presently very few standards to which industry is being held in the development of AI in healthcare. For instance, standards around privacy, security, and confidentiality within health IT is currently in flux. There are also limited regulatory standards on the development and implementation of AI tools, which further complicates how such tools may be accounted for in terms of quality care and outcomes when integrated into Medicare payment considerations.

The APA is also concerned around background development of AI systems that may not include specific populations within standardization samples in AI beta testing/research studies. Presently, some algorithms may be based solely on a certain population for various medical conditions (e.g., men or women; various ethnicities; various socioeconomic groups) resulting in algorithms that may not compute the best treatment options or interventions for patients with unique vulnerabilities (e.g., developmental disorders, suicidal ideation, substance use disorders). Before the technology can be incorporated into Medicare payment models, there needs to be a comprehensive examination (by CMS, the FDA, other entities), of which data are being used to develop any algorithms that influence physician decision-making and patient care. There needs to be an assurance that AI helps patients regardless of one’s race/ethnicity or other social determinants of health and isn’t introducing or magnifying disparities. Finally, before CMS

can begin to incorporate these technologies into Medicare payment, it must first be determined the actual impact on physician cognitive load and the requisite expertise needed to utilize these technologies.

Thank you for the opportunity to comment. The APA welcomes the opportunity to further discuss any of our concerns and recommendations raised in this letter. Please contact Rebecca Yowell, Director of Reimbursement Policy and Quality, at byowell@psych.org.

Sincerely,

A handwritten signature in black ink that reads "Saul Levin, M.D., M.P.A." The signature is written in a cursive, flowing style.

Saul M. Levin, M.D., M.P.A., FRCP-E, FRPsych
CEO and Medical Director
American Psychiatric Association