

800 Maine Avenue, S.W. Suite 900 Washington, D.C. 20024

Board of Trustees 2024-2025

Ramaswamy Viswanathan, M.D., Dr.Med.Sc. .President Theresa M. Miskimen Rivera, M.D. President-Elect Gabrielle L. Shapiro, M.D. Secretary Steve Koh, M.D., M.P.H., M.B.A. Treasurer

Petros Levounis, M.D., M.A. Rebecca W. Brendel, M.D., J.D. Vivian B. Pender, M.D. *Past Presidents* 

Patricia Westmoreland, M.D. *Trustee-at-Large* John C. Bradley, M.D. *Area 1 Trustee* Kenneth B. Ashley, M.D. *Area 2 Trustee* Geetha Jayaram, M.B.B.S., M.B.A. *Area 3 Trustee* Dionne Hart, M.D. *Area 4 Trustee* Heather Hauck, M.D. *Area 5 Trustee* Barbara Yates Weissman, M.D. *Area 6 Trustee* Barbara Yates Weissman, M.D. *Area 6 Trustee* Barbara Yates Weissman, M.D. *Area 7 Trustee* Barbara Yates Weissman, M.D. *Area 7 Trustee* Sudhakar K. Shenoy, M.D. *ECP Trustee* Kamalika Roy, M.D., M.C.R. *M/UR Trustee* Kanneth Certa, M.D. *Parliamentarian* Sarah El Halabi, M.D., M.S.A. *RFM Trustee-Elect* 

#### Assembly 2024-2025

Steven M. Starks, M.D., M.B.A. Speaker A. Evan Eyler, M.D., M.P.H. Speaker-Elect Ray Hsiao, M.D. Recorder

> Administration Marketa Wills, M.D., M.B.A. CEO and Medical Director

September 9, 2024

The Honorable Chiquita Brooks-LaSure, Administrator Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard Baltimore, MD 21244

Re: File Code CMS-1807-P

Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LeSure:

The American Psychiatric Association (APA), the national medical society representing over 38,000 psychiatric physicians and their patients, appreciates the opportunity to comment on the proposed payment and quality policies in the CY 2025 Medicare Physician Fee Schedule and other programs. APA applauds the Administration's ongoing commitment to support coverage for evidence-based treatment for patients with mental health (including substance use) disorders.

APA appreciates the efforts of the Centers for Medicare & Medicaid Services (CMS) to bolster access to mental health care through expanded coverage and improved payments for specific services as proposed in this rule. However, we assert that the Medicare Physician Fee Schedule (PFS) and the Quality Payment Programs (QPP) require further optimization to realize the full potential these policies have to offer. Maintaining a practice, particularly for those psychiatrists treating large numbers of Medicare or dually eligible beneficiaries, has become unsustainable due to annual Medicare payment cuts (2.8% proposed for 2025), potential payment reductions under the Merit-based Incentive Payment System (MIPS), rising practice costs, and long-standing and well-documented policies<sup>1</sup> of private health insurers paying psychiatrists on average 24% less than other physicians. The Medicare Physician Fee Schedule is one of the only Medicare-funded programs that

<sup>1</sup>Mark, T. L., & Parish, W. J. (2024). Behavioral health parity – Pervasive disparities in access to in-network care continue. RTI International. https://www.rti.org/publication/behavioral-health-parity-pervasive-disparities-access-network-care-continue

does not include an inflationary update annually. We urge CMS to call on Congress to enact an annual inflation-based update to the Medicare physician payments tied to the Medicare Economic Index (MEI) through passage of H.R. 2474, the "Strengthening Medicare for Patients and Providers Act."

Psychiatrists can no longer absorb even the most minor cuts, and hard decisions are being made to keep practices who offer in-network care open. Many APA members report they want to continue to participate in Medicare and other networks, but are unable to due to decreasing reimbursement, increasing costs, and uncompensated time lost to overly burdensome administrative requirements (e.g. prior authorization). On a recent listening session, APA members suggested policymakers could facilitate increased participation in Medicare by allowing clinicians the flexibility to accept Medicare assignment on a case-by-case basis, rather than having to opt-out of Medicare entirely. This could be done at the patient level or by setting (e.g. employed clinicians could be opted-in at their employed setting but opted-out in their private practice setting).

Overall, there are many proposals within this regulation that increase access to mental health services, expand coverage and improve quality of care, while also maintaining administrative ease and ensuring payment parity. Our comments focus on opportunities to build on these efforts to enhance access to high-quality mental health care and address the nation's mental health and substance use disorder needs.

# PROVISIONS OF THE PROPOSED RULE FOR THE PFS (Section II)

#### Determination of Practice Expense RVUs (Section II.B.)

#### 2. Practice Expense (PE) Methodology

APA appreciates CMS's efforts to ensure Medicare payments accurately reflect the cost of providing care, including appropriately capturing both indirect and direct practice expense costs. APA has supported the AMA Physician Practice Information Survey (PPIS) data collection process via Mathematica. Last year we urged CMS to refrain from making any changes until that data was available. Recent updates from the AMA, however, have raised concerns that there may be insufficient response from psychiatry to make meaningful decisions about the representative cost of running a psychiatric practice. Unfortunately, we have not yet seen the data collected so cannot speak to the specifics. Ideally, the data must not only represent a range of practice types such as health systems, larger group practices, and small or solo practices, but also it would capture the range of services (e.g., evaluation/management [E/M], psychotherapy, electroconvulsive therapy [ECT], transcranial magnetic stimulation [TMS], esketamine) provided. For each service multiple variables impact the administrative staffing, office size, building requirements (e.g., sound proofing for TMS), and information technology infrastructure. We urge CMS to be mindful of the differences in setting and services to ensure **practices are not disadvantaged because of the evidence-based treatment options they provide.** Once the PPIS data is public, the amount and quality of the data and implications including potential

challenges or need for additional data will be better understood. We encourage CMS to continue considering additional data sources should those be needed.

### c. Clinical Labor Pricing Update

APA members have expressed concerns about the proposed decreases in payment for several services (e.g., esketamine, CoCM) due in part to the implementation of the last round of clinical labor pricing updates. Estimated changes to payments for esketamine administration (Healthcare Common Procedure Coding System (HCPCS) G2082 and G2083) reflect a 7% reduction (over 4% for non-facility PE values) when the proposed conversion factor is applied. Most of the CoCM codes (CPT® 99492, 99493, 99494, and HCPCS G2214) are seeing a reduction of 5-6% overall with most of that (over 4%) due to decreases in the non-facility PE RVUs. These cuts erode the sustainability of practices who currently provide these evidence-based models of care and create a cooling effect for anyone considering implementation of these models. CMS has been supportive of the CoCM for over a decade and while progress has been made in adopting the model, expansion of the model is still needed. Any decrease in these codes' value will slow the adoption of the model and limit the access to mental health and substance use services so many patients need. We urge CMS to consider ways to ensure that reimbursement for these and other mental health services covers the cost of providing care.

# Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (Section II.D.)

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

# d. Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

APA supports the CMS proposal to continue the temporary removal of frequency restrictions for telehealth in specific settings for CY 2025 as additional data is gathered. However, frequency limitations are arbitrary barriers to care, and **we urge CMS to make this change permanent.** Many patients benefit from regular telehealth encounters with psychiatrists in any setting. A hospital or nursing facility in a rural/remote area may not have an attending psychiatrist and may rely on telehealth to bridge this gap in care. Care, including the modality of choice, should be driven by clinical decision making between the physician and the patient (or patient caregiver), with supporting documentation in the record. **We recommend that CMS remove all frequency limitations permanently and allow the decision of the use of telehealth to rest with the clinician.** 

E. Audio-Only Communication Technology to Meet the Definition of "Telecommunications System"

APA supports CMS's proposal to revise current regulations to allow two-way, real-time audio-only communication for telehealth services for beneficiaries in their home when the beneficiary is not capable of or does not consent to the use of video technology. As noted in the proposed rule, this recognizes the variability in the availability of broadband technology, limitations due to functional

impairment of the patient, and individual patient preferences.

#### F. Distant Site Requirements

We support the ability of clinicians to list their practice address, rather than home address, on form 1500 when providing telehealth from home and urge CMS to make this flexibility permanent. Reporting a clinician's home address poses a safety risk and is unnecessary. APA members have reported experiencing safety issues due to exposing personal information to individuals seeking to harm the clinician. This poses a potential retention risk for Medicare participation among psychiatrists, and we recommend that CMS permanently allow practitioners to list their practice address in lieu of their home address.

2. Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

(3) Teaching Physician Billing for Services Involving Residents With Virtual Presence

APA supports CMS's proposal to continue to allow resident supervision through real-time audio and visual interactive telecommunications through December 31, 2025. APA also supports CMS's proposal to allow teaching physicians to have a virtual presence when supervising residents in teaching settings. Throughout the Public Health Emergency (PHE), telehealth delivered by residents was shown to be a safe and effective strategy for maintaining access to care. Additionally, the ability of residency program directors and faculty to supervise multiple residents alleviates the significant shortage of psychiatric faculty currently. However, the proposed virtual supervision provisions requiring residents to not be with the patient presents challenges for psychiatrists. Specifically, the provision could impact the ability of clinicians to supervise care overnight when the resident is with the patient, and in rural areas where supervising clinicians are not available. Additionally, if a supervisor is ill but able to supervise remotely, the resident would need to continue with clinic including in-person and remote visits. APA supports these efforts and asks CMS to: 1) permanently codify virtual supervision of residents, and 2) allow virtual supervision in those instances where the patient and resident are co-located and the supervising clinician is joining remotely from a separate location.

#### E. Valuation of Specific Codes (Section II.E.)

#### 4. Valuation of Specific Codes for CY 2025

(18) Telemedicine Evaluation and Management (E/M) Services (CPT<sup>®</sup> Codes 9X075, 9X076, 9X077, 9X078, 9X079, 9X080, 9X081, 9X082, 9X083, 9X084, 9X085, 9X086, 9X087, 9X088, 9X089, 9X090, and 9X091)

APA thanks CMS for supporting the request to not recognize the 16 new Telemedicine Evaluation and Management (E/M) Services (CPT<sup>®</sup> Codes 9X075, 9X076, 9X077, 9X078, 9X079, 9X080, 9X081, 9X082, 9X083, 9X084, 9X085, 9X086, 9X087, 9X088, 9X089, 9X090). We urge CMS to finalize the proposal to

use the existing outpatient e/management services (CPT<sup>®</sup> codes 99202-99215) in conjunction with the appropriate place of service code or modifier to describe services provided by telehealth, including audio-only care. This approach avoids the complexity of introducing new standalone telehealth codes, ensures payment is the same for equivalent work, allows CMS to track the use of telehealth by modality, and aligns with established CPT<sup>®</sup> and CMS guidelines that if existing codes adequately describe the service, and new codes should not be created.

Payment parity is supported by 1834(m)(2)(A) of the Social Security Act,<sup>2</sup> affirmed by CMS in their comments in the CY 2024 final rule regarding payment accuracy for behavioral health telehealth services<sup>3</sup> and is reinforced by actions at the state level where over half of all states have implemented some form of payment parity for telehealth services. <sup>4</sup> APA requests that CMS affirm that telehealth payments for services provided outside a facility setting will be paid at the non-facility (practice expense) rate, just as payments for in-person care are.

The expansion of telehealth has been a cornerstone in improving access to psychiatric care, demonstrating efficacy comparable to in-person visits even for high-acuity concerns. The convenience and privacy of receiving treatment at home, the flexibility in scheduling, and the reduction of stigma associated with seeking mental health services have significantly contributed to patient engagement and long-term recovery, encouraging individuals to seek and continue care they might otherwise avoid. Most psychiatrists will be treating patients in a hybrid environment where patient need drives how care is provided. APA does not support coding constructs that delineate CPT<sup>®</sup> codes by modality, and instead supports the use of modifiers to identify telehealth delivery for the purposes of research and analysis.

# G. Enhanced Care Management (Section II.G.)

2. Advanced Primary Care Management (APCM) Services (HCPCS Codes GPCM1, GPCM2, and GPCM3) and 3. Request for Information: Advanced Primary Care Hybrid Payment

<sup>2</sup> (m) Payment for Telehealth Services.—

(2) Payment amount.—

<sup>(1)</sup> In general. —The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1861(r)) or a practitioner (described in section 1842(b)(18)(C)) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term "telecommunications system" includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.

<sup>(</sup>A) Distant site.—The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system.

<sup>&</sup>lt;sup>3</sup> Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies, Vol. 88, F.R., 78875, (Finalized Nov 16, 2023) https://www.federalregister.gov/d/2023-24184

<sup>&</sup>lt;sup>4</sup> https://www.ama-assn.org/system/files/ama-state-telehealth-policy-trends-2023.pdf

APA supports an Advanced Primary Care Model that incentivizes and provides the financial sustainability for implementation of evidence-based models of care (e.g., measurement-based care [MBC], Psychiatric CoCM) shown to improve mental health outcomes in the primary care setting.<sup>5</sup> Implementation of measurement-based care goes beyond screening and referral to improve care by employing repeated use of validated rating scales to serially assess symptoms over time and track clinical progress. At a practice level, MBC, along with data registries, facilitates population-based care and enables a pro-active approach by the practice to identify patients by various clinical sub-categories (i.e. those who are not improving or those have not stayed engaged in care). As a routine part of practice, primary care practices should implement MBC following a positive screen for a mental health condition, just as they do when measuring a diabetic patient's A1C level. CoCM, which includes MBC, takes a team-based approach to managing mental health care in the primary care setting. A psychiatric consultant working collaboratively with a care manager, monitors the progress of a population or panel of patients, making treatment recommendations to the primary care physician for patients not improving. The primary care physician executes the clinical recommendations. Not only is the psychiatric consultant able to care for more patients than in traditional psychiatric practices, the primary care clinician's knowledge base increases and the primary care clinician appreciates the support provided by their psychiatric colleagues leading to increased primary care physician satisfaction. This model is also show to improve patient outcomes. APA recommends providing implementation support and ongoing funding for these models of care in an Advanced Primary Care Model, which will allow practices to establish the team, develop the caseload, build the registry infrastructure, reduce current administrative barriers related to timebased billing, and provide an evidence-based framework to improve outcomes. We urge CMS to engage with both the primary care and mental health community in the continued development and rollout of this model.

#### Advancing Access to Behavioral Health Services (Section II.I.)

1. Safety Planning Interventions and Post-Discharge Telephonic Follow-up Contacts

We applaud CMS for proposing a reimbursement framework that describes the work of Safety Planning Interventions and Follow-up Contacts. Coverage of these services is a huge step forward in advancing evidence-based interventions that are critically important for Medicare's most vulnerable patients. However, APA has several recommendations that would simplify the billing process and ensure the time spent providing care is accurately captured. Implementation of other services such as Complex Chronic Care Management, which had to overcome overly burdensome requirements and low adoption rates in order to realize the full potential of these services, can serve as a learning experience. We encourage CMS to broaden the definition of who can provide these services to include trained clinical staff and to build in some flexibility so the codes can be billed in a broad range of settings. The APA suggested changes create a structure that is flexible enough to account for the range of billing relationships/requirements present in practice and could reduce the number of billing challenges that may arise because of payment rules related to setting or the relationship between clinicians. Several of

<sup>5</sup> Wray LO, Oslin DW, Leong SH, et al. Enhancing Implementation of Measurement-Based Mental Health Care in Primary Care: A Mixed-Methods Study. Psychiatric Services. 2023;74(7):746-755. doi:10.1176/appi.ps.20220140; https://doi.org/10.1176/appi.ps.20220140 Accessed 8.29.24 these modifications also allow us to gather data which we can use in considering any future refinements.

To encourage uptake of these services, APA strongly recommends the following modifications:

- Broaden the definition of who can perform the service to include trained clinical staff.
- Maintain the crosswalk to the psychotherapy for crisis code (CPT<sup>®</sup> 90839, proposed RVW 1.09) but allow it to be billed in units of 20 minutes.
- Establish this as a standalone (XXX) code to allow the service to be billed in the broad range of settings for which it is intended.
- Unbundle the Post-Discharge Follow-up Calls to allow the billing of the service when performed.

# Safety Planning Interventions (SPI)

We have the following recommendations in response to CMS's request for feedback on HCPCS code GSPI1, Safety planning interventions, including assisting the patient in the identification of the following personalized elements of a safety plan: recognizing warning signs of an impending suicidal crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; contacting mental health professionals or agencies; and making the environment safe; (List separately in addition to an E/M visit or psychotherapy):

- APA supports the use of trained clinical staff working under the licensed practitioner's supervision, which extends, rather than limits, the ability to provide this evidence-based intervention and mirrors protocols in clinical studies. This is particularly important in the emergency department and other settings such as primary care where the billing practitioner is more likely to refer patients to their clinical staff to perform these services.<sup>6</sup>
- We suggest adding "form" or "documentation" to the code descriptor for clarity. GSPI1, Safety planning interventions, including assisting the patient in the identification of the following personalized elements of a safety plan <u>form/documentation</u>: recognizing warning signs of an impending suicidal crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; contacting mental health professionals or agencies; and making the environment safe; (List separately in addition to an E/M visit or psychotherapy). The elements listed are items in the form completed as part of the process and given to the patient. Relevant professional associations will develop a complete description of work to be included in member education materials.
- We support the crosswalk to the CPT<sup>®</sup> code 90839, psychotherapy for crisis, but recommend that CMS allow this code to be billed in 20-minute units, with a maximum number of six units/day. We support the crosswalk identified (CPT<sup>®</sup> 90839, psychotherapy for crisis) which is

<sup>6</sup> Stanley B, Brown GK: Safety Planning Intervention: a brief intervention to mitigate suicide risk. *Cogn Behav Pract* 2012; 19:256–264

a time-based code with similar intensity and effort. Experts estimate that 20 minutes is the <u>minimum</u> amount of time needed to perform SPI. Allowing services to be billed in 20-minute units will ensure there is sufficient time with the patient, which can vary based on patient complexity and involvement of others. This approach, if finalized, would provide utilization data (e.g., length of time by setting) that can be considered for future refinements. Billing would be limited to six units.

- APA strongly encourages CMS to establish the SPI code as a stand-alone service, billable on its own. There are times and settings in which this service will be performed on its own (e.g., crisis centers, primary care, emergency departments), and times where SPI will be provided in addition to another service (e.g., E/M or psychotherapy). We want to ensure there is a billing mechanism that meets both scenarios. The elements of SPI are separate and distinct processes with no overlap with other services billed on the same day. Much like a separate test in the primary care setting, this work is discrete and can be distinguished from other activities on the same day. By not creating a standalone option, additional and unnecessary services may be provided just to bill this code or the service may not be provided at all. CMS would apply standard billing requirements (i.e., no double counting of time) if the service is performed on the same day as a psychotherapy encounter or within the month when another time-based code (e.g., collaborative care service, chronic care management) is billed.<sup>7</sup>
- SPI will be billed by a mix of clinicians including mental health clinicians. As noted above we strongly support the use of clinical staff, under the direction of the billing professional, to provide this service.

#### Post-Discharge Follow-up Contacts

We have the following recommendations in response to CMS's request for feedback on HCPCS code GFCI1, Post discharge telephonic follow-up contacts performed in conjunction with a discharge from the emergency department for behavioral health or other crisis encounter, per calendar month.

• We support CMS's proposal to pay for post-discharge follow-up contacts, though we strongly recommend these services be unbundled and billed as stand-alone telephone calls. CMS has proposed a bundled service that accounts for completed calls of 10-20 minutes each over a month. CMS has also indicated that the code could be billed as soon as the first call is completed. While APA supports coverage of follow-up contacts, a simpler and more data-driven option would be to allow practices to bill the service each time a call is completed with up to four calls per month for a minimum of six months. This change would provide the necessary flexibility given that the frequency of calls within the month depends on multiple factors including patient need, the ability to engage the patient and the time of the month the patient enters care. Patients may be difficult to engage, making it hard to successfully complete all four calls in one month. Patients entering care at the end of the month may only receive one call before the start of the next month. Requiring a specific number of calls per calendar month could mean that the services are not billable, while also increasing the administrative burden to

track completed telephone calls. Practices will not implement the intervention if there is a significant risk of uncompensated care. Unbundling the service, with appropriate adjustments to the payment, would focus the timing of the call on meeting the clinical needs of the patient. Billing data will provide the frequency data per patient per month and information on any variation by setting or geographic region and can be considered as part of any future refinements of the codes. If CMS is concerned about overuse, we suggest limiting the number of calls (for billing purposes) per month to four. Studies on this intervention showed follow-up that lasted up to 12 – 18 months.<sup>8</sup> We recommend at least 12-18 months but no less than a 6-month duration. We support CMS's proposal as to the number of minutes per call (10-20) required to perform this work. We recommend a crosswalk to CPT<sup>®</sup> code 99490, Chronic Care Management, first 20 minutes (RVW 1.00) which is more in line with the work performed. (RVW 0.75 adjusting the time to 15 minutes).

• We encourage CMS to allow billing of these calls to include when patients are discharged from psychiatric inpatient units/facilities. Transitioning from inpatient care into the community is one of the most delicate times in a psychiatric patient's care journey. Follow-up contact after hospitalization keeps patients engaged in their care which is critical given the delays patients experience accessing mental health care, and in light of other challenges such as anxiety, coping difficulties, and lack of treatment adherence. Outreach through post-discharge follow-up contacts following any emergency department or inpatient hospital stay bridges the gap until the patient is ready and able to access outpatient care.

#### 2. Digital Mental Health Treatment (DMHT) - CORRECTED

There is insufficient evidence of efficacy for any of the DMHT devices currently on the market, including those with FDA approval. The FDA approval process must be improved to better evaluate DMHT devices and to make FDA approval of devices more meaningful. Paying for these devices is premature and not an appropriate use of Medicare funds.

Real-world longitudinal data, statistically significant effect sizes, and studies using new research models are steps towards making FDA approval more meaningful. These devices are marketed as tools to increase access to care for everyone, and it is therefore imperative that these devices are studied at-scale and implemented within populations researched. In the few cases where these devices have been tested at-scale, we have learned about potential concerns, such as increasing risk of harm.<sup>9</sup>

Data has shown a lack of sustained engagement on the part of patients both within the clinical trial environment, as well as in general use of publicly available devices.<sup>10</sup> Furthermore, the onus is currently

<sup>8</sup> Fleischmann A, Bertolote JM, Wasserman D, et al. Effectiveness of brief intervention and contact for suicide attempters: a randomized controlled trial in five countries. *Bull World Health Organ*. 2008;86(9):703-709. doi:10.2471/blt.07.046995 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2649494/) <sup>9</sup> https://jamanetwork.com/journals/jama/fullarticle/2789028

<sup>10</sup> Nwosu A, Boardman S, Husain MM and Doraiswamy PM (2022) Digital therapeutics for mental health: Is attrition the Achilles heel? Front. Psychiatry 13:900615. doi: 10.3389/fpsyt.2022.900615

on the clinicians only in the event of patient harm or malpractice. The devices are also not HIPAAcovered entities and, accordingly, are held to very minimal standards of data privacy. There is currently a lack of awareness of the risks and harms for DMHT devices. In the realm of digital mental health technologies, there is a common perception that wellness-focused tools like mindfulness apps are considered low-risk and are not required to provide extensive evidence of effectiveness. However, evidence for harm from even these wellness-focused treatment tools is mounting including a 2022 study revealing that those with suicidal ideation who were randomized to an online low-intensity format of behavioral therapy had higher rates of nonfatal or fatal self-harm.<sup>11</sup>

Due to greater accessibility, flexibility, and convenience for patients compared to in-office care, mobile patient-driven mental health and wellness support and self-management tools are an appealing approach for low to moderate acuity mental health care. However, the rapid proliferation and minimal regulation of these solutions pose challenges to the appropriate clinical application of these tools. Balancing these risks and benefits requires clinical judgment and an understanding of the landscape of mental health technology.

To date, there is no clear, practical definition of digital therapeutics that applies a rigorous standard of evidence of safety and effectiveness required prior to codifying reimbursement for these products. As CMS has acknowledged, there are challenges related to pricing of the supply due to the varying pricing structures and a vast array of purchasers (e.g., insurance plans, health systems, employers, state/local governments, consumers, and clinicians) adding a level of complexity to appropriate valuation that could impact uptake. There is also not enough evidence to determine the efficacy of these therapeutic devices, how they are currently being used by patients nor whether 20 minutes (as specified in the proposed codes) is adequate time to provide care management.

# We do not support payment at this time. In the event that CMS finalizes the HCPCS coding proposal, the codes should retain the FDA approval requirement.

In addition, APA emphasizes that:

- Digital therapeutics should not replace evidence-based clinical care.
- Digital therapeutics do not always consider key elements of digital equity including access to smartphones and adequate internet connectivity or data, digital literacy, and comfort with digital interventions, including privacy and security, and physical access to technology (e.g., for people with visual impairments).

<sup>11</sup> Torous J, Firth J, Goldberg SB. Digital Mental Health's Unstable Dichotomy—Wellness and Health. JAMA Psychiatry. 2024;81(6):539–540. doi:10.1001/jamapsychiatry.2024.0532

- Digital therapeutics or digital interventions need to be evaluated for the patient's specific purposes in concert with the clinician to assess appropriateness for meeting the patient's needs and should not replace clinical care.
- CMS should consider adopting a framework similar to the APA App Advisor Evaluation Model<sup>12</sup> in assessing the usage of apps in the Medicare population.

# OTHER PROVISIONS OF THE PROPOSED RULE (Section III)

# Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (Section III.B.)

2. General Care Management Services in RHCs and FQHCs

# C. Proposed Payment Policy for General Care Management Services

The Psychiatric Collaborative Care model (CoCM) community reports that FQHCs/RHCs are not implementing psychiatric collaborative care programs because of existing financial barriers related to the current payment structure. The valuation and billing requirements of the HCPCS G0512 are such that implementation in these settings is seen as not being financially viable. For example, the current structure does not pay for the full amount of time spent providing care and falls short of payments FQHCs/RHCs can receive when billing their Prospective Payment System (PPS) encounter rate. Unlike the CPT<sup>®</sup> codes that allow for the billing of the service once the mid-point of time plus one minute is passed (36 minutes for the first month and 31 minutes for subsequent months), FQHCs/RHCs are only able to bill once the full minute allocation is met (70 minutes for the first month and 60 minutes for subsequent months). As a result, entities are not able to capture the time spent providing care for those months that fall below the 70/60-minute mark. They are also unable to bill the HCPCS G2214 to capture minutes at the low end (16-69/59 minutes), and they are unable to bill for any added time at the high end (more than 70/60 minutes) using add-on CPT<sup>®</sup> code 99494, which is not recognized within this structure. Therefore, there is a substantial amount of time where work being performed goes uncompensated either because the time threshold is not met or is exceeded. For example, in instances where care is started at the end of the month it is quite likely the minimum time threshold may not be met. This is also the case as the patient is getting better and easing out of the program at the end of their course of care. There are also instances where a patient has complex needs that require added time, which goes unpaid.

FQHCs/RHCs also have the ability to bill other mental health services multiple times a month using CPT<sup>®</sup> codes that pay their PPS encounter rate, a rate that is substantially higher than the rates for CoCM using HCPCS G0512. This creates an additional disincentive to implementing CoCM. Despite significant evidence that it improves care as compared to usual care,<sup>13</sup> CoCM is reimbursed at a lower rate than other services in this setting and costs more to provide. This effectively eliminates a site of service that

 <sup>&</sup>lt;sup>12</sup> https://www.psychiatry.org/psychiatrists/practice/mental-health-apps/the-app-evaluation-model
<sup>13</sup> https://aims.uw.edu/wordpress/wp-content/uploads/2023/06/Comparing-Collaborative-Care-to-Usual-Care\_121719.pdf

cares for a high percentage of patients with mental health disorders and has an infrastructure that is better suited than many to support implementation. **CMS has recognized the need and value of making changes to how care is billed under the HCPCS G0511 in this proposed rule by allowing FQHCs/RHCs to bill individual CPT® codes rather than the HCPCS G0511 to account for the time and work involved.** We urge CMS to do the same to support the adoption of CoCM and suggest multiple ways to achieve this goal:

- 1. Allow FQHCs/RHCs the option of billing the CPT<sup>®</sup> /HCPCS codes (99492-99494, G2214) according to the established CPT<sup>®</sup> guidelines with respect to time; this includes having the ability to use the add-on code CPT<sup>®</sup> 99494 to capture added time as needed.
- 2. Allow FQHCs/RHCs to bill HCPCS G2214 (Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month) in multiple units per month.
- 3. Allow FQHCs/RHCs to bill the HCPCS G2214 (Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month) in addition to the existing HCPCS G0512.

This would be in line with the Administration's goal of increasing access to mental health care in primary care, enable FQHCs/RHCs to receive more appropriate payment for the time spent providing services, and significantly improve outcomes for their patients.

# D. In-Person Visit Requirements for Remote Mental Health Services Furnished by RHC and FQHCs

Americans continue to rely heavily on telehealth for access to treatment for mental health conditions, with mental health representing 68.2% percent of all telehealth visits according to a May 2023 APA survey. The data indicated that the majority (82%)<sup>14</sup> of telehealth is delivered in video formats. Some psychiatrists reported that they resort to audio-only when video does not work to ensure access for their patients. These flexibilities have allowed patients to maintain their care despite returning to inperson work or moving farther away from city centers; has allowed new patients to access care that otherwise were prevented due to physical, clinical, financial, or social barriers; and has allowed clinicians to offer care in the way that best fits the patient's needs and preferences. While clinicians enjoy and appreciate the additional flexibility, which is a valuable tool in combatting the shortage of psychiatrists and clinicians more broadly, the largest benefit accrues to patients.

Telehealth treatment has been found to be as safe and effective as in-person care even for high-acuity psychiatric concerns, and increases access to care in instances of stigma, rural location, mobility challenges, and other health-related social needs.<sup>15</sup> APA urges CMS to permanently remove a mandatory in-person visit requirement for Medicare beneficiaries prior to initiating or maintaining telemental health care with a psychiatrist, contributing to equitable access to crucial, safe, and effective telepsychiatry.

<sup>&</sup>lt;sup>14</sup> Worthen A, Torous J, Khan S, Hammes N, Rabinowitz T. Telepsychiatry Current Practice and Implications for Future Trends: A 2023 American Psychiatric Association Member Survey. Telemed J E Health. 2024 Aug 12. doi: 10.1089/tmj.2024.0042. Epub ahead of print. PMID: 39133114.

<sup>&</sup>lt;sup>15</sup> <u>Telehealth Treatment of Patients in an Intensive Acute Care Psychiatric Setting During the COVID-19</u> Pandemic: Comparative Safety and Effectiveness to In-Person Treatment.

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

APA supports CMS in making permanent the telemedicine flexibilities for OTPs and the proposal to establish payments for Social Determinants of Health risk assessments as part of the intake activities. CMS' proposal continues to build on previous rule making, allowing OTPs to provide substance use counseling and initiation of buprenorphine treatment with audio-video and audio-only technologies. CMS has previously noted that Medicare beneficiaries who are older than 65 years-old, racial/ethnic minorities, dual-enrollees, or living in rural areas, or who experience low broadband access, low-income, and/or not speaking English as their primary language, are more likely to be offered and use audio-only telemedicine services than audio-video services. Therefore, the proposal to permanently allow OTPs to furnish periodic assessments via audio-only should be finalized to ensure continuity of treatment. APA also encourages CMS to finalize the proposal that would allow the initiation of methadone treatment via audio-video technologies to advance access to life saving treatment.

#### UPDATES TO THE QUALITY PAYMENT PROGRAM (Section IV)

APA thanks CMS for the changes that will reduce clinician burden for those psychiatrists who report under MIPS. We support the changes that include freezing the threshold for negative payment adjustment at 75, reweighting categories where data are unable to be obtained due to circumstances outside the control of the clinician, and eliminating the automatic removal of hardship exemptions if data are accidentally submitted.

#### (1) Transforming the Quality Payment Program

CMS has indicated they are considering the development of an ambulatory care model that is designed to connect payment to the performance of specialists who deliver care in ambulatory settings. The stated goal is to increase integration between specialty and primary care in an accountable way. The potential model would use MIPs Value Pathways (MVPs) as the foundation for accessing specialist performance.

As currently described, the proposed model is aspirational. **MVPs as they exist today have not lived up to their original aims, and as such we do not support using them as the foundation of the new model as described.** Within the Mental Health and Substance Use MVP (the specialty MVP for psychiatry), for example, there is no real link between the quality measures and cost measures. At present, the MVP is a long list of every measure related to mental health EXCEPT for the two screening measures for tobacco and alcohol, the most abused substances in the US. There is nothing that encourages behavioral health integration including collaborative care, which would help achieve the stated goal of delivering longitudinal care in an accountable manner and supporting greater integration between specialty and primary care. Finally, there's no link to the cost measures for most quality measures in the MVP; even if you may satisfy the reporting requirements, there is no assurance that this will have a positive impact on the cost component. As we have said in prior comments, this puts clinicians at risk for being accountable for things they cannot control. We are interested in continuing to work with CMS to refine the current MVP and encourage CMS to consider other options such as the concept previously raised

focusing on depression care, a Depression MVP focused on mild-moderate depression that includes measures related to depression, a requirement for the use of MBC to measure and improve outcomes, and tied to a cost measure focused on that specific population.

#### c. Mandatory Subgroup Reporting Requirement

Because data is not freely available, we do not know how many psychiatrists practice in large practices that are not also Alternative Payment Models (APM). We encourage CMS to identify ways this data, and other relevant data, is readily available so organizations can provide more informed feedback on RFIs. We believe that a subgroup reporting requirement will add significant burden to large multispecialty practices that have a small number of psychiatrists who will need to collect and report data on mental health measures. Most practices do not have the information technology infrastructure to report new measures, especially if they are not already benchmarked. We are concerned this could have the unintended consequence of breaking up multi-specialty practices and moving away from integrated care, rather than fostering it.

With respect to small practices, we agree with CMS's proposal to not make subgroup reporting mandatory; we do support it being an option. For practices with some but not significant variation in practice type, one MVP may be sufficient and less burdensome to report. There may be other settings that include other specialties for which subgroup reporting would be a better fit. For example, there may be a 14-person interventional psychiatric practice that includes ten psychiatrists and four anesthesiologists. It would not be appropriate for the anesthesiologists to report under the Mental Health MVP, so having a way to report under a different MVP, one specific to anesthesiology in this example, would be useful.

Given the concerns noted above, **APA strongly supports the retention of traditional MIPS and does not believe the field will be ready for exclusive MVP reporting by 2029.** Removing traditional MIPS pigeonholes clinicians into reporting measures that are potentially less meaningful to their practices and will not improve care. We encourage CMS to incentivize innovation in improving mental health outcomes; opportunities for innovation may be lost if CMS is too prescriptive about what can be reported.

Thank you for your review and consideration of these comments. If you have any questions or would like to discuss these comments in more detail, please contact Becky Yowell (qualityandpayment@psychiatry.org), Director, Reimbursement Policy and Quality.

Sincerely,

MO, MOA, FAPA

Marketa Wills, MD, MBA, FAPA CEO and Medical Director American Psychiatric Association