AMERICAN PSYCHIATRIC ASSOCIATION

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September 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1784-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1784-P; Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure:

The American Psychiatric Association (APA), the national medical society representing over 38,000 psychiatric physicians and their patients, appreciates the opportunity to comment on 2024 payment policies in the Medicare Physician Fee Schedule and other programs. APA supports the Administration's work to increase access to and quality of care through aligned incentives; ongoing coverage of technology-enabled, community-based care; and collaborative care arrangements. APA also appreciates the Administration's ongoing commitment to evidence-based treatment and coverage through the solicitation of data and expert input. Our comments focus on opportunities to build on these successes to maintain access to high-quality mental health care and enhance our ability to address the nation's mental health and substance use disorder crisis.

Medicare Physician Fee Schedule and Quality Payment Program Framework/Methodology

APA appreciates the efforts of CMS to bolster access to mental health care through improved coverage including payments, however, the legal framework governing the Medicare Physician Fee Schedule (PFS) and the Quality Payment Program (QPP) continues to undermine the impact of the proposed policies, and as a result has a direct impact on the ability for psychiatrists and other physicians to maintain a viable practice as a participating provider under Medicare. In many ways these policies such as the statutory budget neutrality requirements, sequestration requirements, and statutory freeze on annal updates under the PFS and the increase in the Merit-based Incentive Payment System (MIPS) performance threshold MIPS put psychiatric

practices at risk given the potential for significant negative adjustments. A March 2022 JAMA article looking at psychiatrists' performance under MIPS concluded that "psychiatrists had significantly lower 2020 MIPS performance scores, were penalized more frequently, and received fewer bonuses."[1] The article went on to urge policymakers to evaluate whether the performance measures actually assess performance. **We urge CMS to work with Congress and other stakeholders to address the long-standing problems within the framework of the payment and quality system to ensure physicians can sustain their practice.** While we are pleased with CMS' focus on ways to improve access to mental health and substance use disorder services, specifically psychiatric care, there are contradictory proposals within this rule that would work directly against that goal. **We also urge CMS to use their policy levers to delay implementation of policies we know will have negative implications for psychiatrists and others and the unintended consequence of having a chilling effect on providing care to Medicare beneficiaries. This includes delaying the implementation of the proposed behavioral health MVP and any associated cost measures.**

Soliciting Public Comment on Strategies for Updates to Practice Expense Data Collection and Methodology (Section II.B)

APA supports the collaborative work CMS, AMA and others have undertaken to update the indirect practice expense data and improve the existing methodology used to calculate what is a significant (estimated at 30-46%) portion of the overall Medicare payment. It is critical to capture current costs, including new items related to technology/AI, etc.

APA supports the AMA's Physician Practice Information survey which is designed to update the data currently used to calculate indirect practice expenses. It will be important to monitor the data collection efforts to address any challenges in a timely way. This includes ensuring adequate representation by a range of practice types. We have seen an increase in the number of practices that could generically be called interventional psychiatry; those offering services such as ECT, TMS, Esketamine for treatment resistant depression and other disorders. The practice expense profile is different due to staffing, equipment, and supply costs which invariability would have an impact on indirect costs as well. **We urge CMS and AMA to be mindful of these practices to ensure they are not disadvantaged because of the evidence-based treatment options they provided.** CMS has chosen not to use the standard methodology in the calculation of the indirect values for two of these services (TMS and Esketamine) even though billing patterns reflect that psychiatrists make up the vast majority of those billing for the service. The system must appropriately recognize the full range of practice types so as not to risk diminishing or eliminating effective treatment options. Once the process is complete, we will have a better understanding as to the amount and quality of the data, and implications including potential challenges or need for alternatives.

Consideration should be given to maintaining a cohort of practices that participate in this process on a routine basis (every five years) to incentivize and ease any administrative burdens associated with responding on a routine basis. This cohort could be combined with a random group of new survey

[1] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2790543

participants. CMS should also consider implementing a process that can more readily address unforeseen financial challenges such as rising staffing costs, high inflation or a pandemic.

Coverage for Telemental Health (Section II.D)

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 treatment in May 2023.[2] **APA supports the codification of the Consolidated Appropriations Act, 2023, extensions of telehealth capabilities, including the delay of in-person requirements for telemental health, the allowance of audio-only telemental health care, and the allowance for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) to be reimbursed for rendering telehealth services.** APA member survey data indicate that the majority (82%) of telehealth is delivered in video formats. Some psychiatrists reported that they only 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 in-person work or moving farther away from city centers; has allowed new patients to access care that otherwise were prevented due to physical, 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.[3] **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.**

Places of Service

APA strongly supports the maintenance of codes billed with POS 10 ("Telehealth Provided in Patient's Home") paid at the non-facility rate, constituting the same level of coverage as if the care had been provided in-person. Most telepsychiatry is provided in hybrid settings with practitioners maintaining physical locations in addition to offering virtual care, incurring the same level of practice expenses as they would be in an in-person environment.[4] Negative implications of reduced reimbursement include a decrease in clinicians delivering telehealth, reductions in a clinician's ability to get and maintain telehealth technology, and potential cherry-picking of patients with the ability to travel to an in-person visit, all of which create risks to health equity, access, and quality. **APA urges CMS to permanently maintain payment for telehealth provided to patients' homes at the same rate as if the service had been delivered in person to maintain quality of and access to care in rural and other under-resourced settings.**

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[2] Monthly Telehealth Regional Tracker, May 2023.

[3] Telehealth Treatment of Patients in an Intensive Acute Care Psychiatric Setting During the COVID-19 Pandemic: Comparative Safety and Effectiveness to In-Person Treatment.

[4] Telepsychiatry Practices Inform Importance of Maintaining Reimbursement Rates for Telehealth in the 2024 Medicare Physician Fee Schedule.

APA supports continuing to use the codes one would bill for in-person care with the addition of the appropriate place of service code if care is provided via audio/video or audio-only in lieu of the new CPT family of codes. It is administratively simpler and has been effectively done this way since telehealth was introduced.

Virtual supervision of residents

APA recommends that the ability for residents to deliver telehealth services under virtual supervision be applied permanently. Residents delivering telehealth has been demonstrated throughout the COVID-19 PHE to be a safe and effective strategy for maintaining access to care. Further, residents delivering telehealth with supervision from a teaching physician ensures that they are trained for telehealth service delivery when they enter the physician workforce. The teaching physician is ultimately responsible for the clinical outcomes of the care provided by residents, and the resident accordingly is held to the same clinical standard as the teaching physician providing care themselves. Perhaps most importantly, **virtual supervision of residents is a key retention tool for highly-qualified attending physicians and will help curb the drastic workforce shortage facing psychiatry.** Virtual supervision reduces burdensome commuting time, especially between multiple facilities, and allows specialists to work with the populations that need them most.

Furthermore, guardrails exist through the Accreditation Council for Graduate Medical Education (ACGME) have standards and systems that will ensure patient safety and oversight of residents when virtual supervision of residents occurs. ACGME sets forth extensive program requirements, including requirements related to supervision and recognizes that supervision may be exercised through a variety of methods, as appropriate to the situation, including through telecommunication technology. The program must demonstrate that the appropriate level of supervision is in place for all residents and is based on each resident's level of training and ability guided by milestones, as well as patient complexity and acuity. The faculty must assess the knowledge and skills of each resident and delegate to the resident the appropriate level of patient care authority and responsibility, and each resident must also know the limits of their scope of authority. ACGME and the medical education community work hard to monitor, report, and address any issues related to workload, patient safety, medical error, resident well- being and burn-out, professionalism, and resident learning and outcomes.

In tandem, maintaining virtual direct supervision increases access to quality care. For example, virtual supervision allows physicians to supervise clinical staff across multiple campuses, which increases patient access to care; teaching physicians can access patient data during the encounter for more thorough supervision; and patients can more easily maintain continuity of care. APA conducted listening sessions with partner organizations – the American Association of Chairs of Departments of Psychiatry and the American Association of Directors of Psychiatric Residency Training – on this topic and **no departments of psychiatry that APA has yet spoken to support the removal of virtual supervision of residents.** APA is working with departments of psychiatry and psychiatric residency training programs to supply data to CMS about relative quality and safety of virtually-supervised residents to inform the maintenance of this flexibility, and we offer the expertise of department directors to CMS in understanding the landscape of virtual medical education and ensure ongoing access to and quality of care. If CMS continues to wish to

remove this flexibility after 2024, CMS should provide data and a rationale for any care quality issues justifying this decision.

APA and its partners also **do not support the proposed rule to only allow virtual supervision in cases where the patient, resident, and teaching physician are in three different locations.** Rather, departments of psychiatry use multiple configurations of care delivery and supervision to ensure appropriate care by the resident and supervision by the teaching physician, and these additional options create no additional quality or effectiveness concerns for the patient. The most common of these configurations is the resident and patient collocated in a physical site with the teaching physician offsite, which allows: (1) supervision by the most appropriate teaching physician (e.g., a subspecialist in geriatric or addiction psychiatry) when that teaching physician may not be able to have a physical presence in the facility; (2) the accommodation of patient preference if patients would prefer to receive their care in-person; and (3) the development of an authentic, trusted physician-patient relationship with the attending maintaining an unobtrusive virtual presence for oversight and teaching. As with all such policies, allowing residency training programs to mimic the reality of care delivery to the greatest extent possible – including both virtual and in-person care supervised by the most appropriate teaching physician – equips the resident with the most useful training for caring for patients independently.

Evaluation and Management Visits (Section II.F)
Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation (Section II.F.2.b)
See below (Section II.J.5)

Request for Comment About Evaluating E/M Services More Regularly and Comprehensively (Section II.F.2.c)
The following is APA's feedback to CMS on the Request for Comment about evaluation of E/M services.

"We are particularly interested in ways that CMS could potentially improve processes and methodologies, and we request that commenters provide specific recommendations on ways that we can improve data collection and to make better evidence-based and more accurate payments for E/M and other services."

APA supports having the ability to submit additional data to CMS for consideration. We encourage CMS to develop and publicize a process for data submission as well as provide examples of the types of data to be considered. This would include naming alternative data sets that could be useful across multiple/all physician groups.

"We are also interested in recommendations that would ensure that data collection from, and documentation requirements for, physician practices are as least burdensome as possible while also maintaining strong program integrity requirements."

APA supports ongoing reductions in administrative burdens associated with data collection. It may be worthwhile for CMS to explore how technology can support data collection activities.

"Finally, we are also interested in whether commenters believe that the current AMA RUC is the entity that is best positioned to provide -recommendations to CMS on resource inputs for work and PE (Practice Expense) valuations, as well as how to establish values for E/M and other physicians' services; or if another independent entity would better serve CMS and interested parties in providing these recommendations."

The work of the RUC, including the review of data and the deliberative process, is a useful component in the evaluation of work, time, practice expenses, and complexity and intensity of the services described. Recommendations from the RUC should be considered along with any supplemental data presented from interested stakeholders.

Split (or Shared) Visits (Section II.F.3)

APA supports maintaining the current definition of "substantive portion" that allows for use of either one of the three key components (history, exam, or MDM) or more than half of the total time spent to determine who bills the visit.

Implementation of Section 4123 of the CAA, 2023, Improving Mobile Crisis Care in Medicare auxiliary personnel (Section II.J.2)

APA appreciates CMS' efforts to expand access to crisis services. Services such as crisis call centers, mobile crisis teams, crisis facilities (like acute psychiatric unit and crisis residential programs), and post-crisis wraparound have been proven in research studies and clinical experience to provide a host of benefits, including decreased suicidality, emergency department (ED) costs, and hospitalization. Meeting the needs of those with mental illness or substance use disorders depends on strengthening and funding the mental health infrastructure by treating evidence-based, community crisis systems as essential community services. Appropriate payment for these essential services is a required component.

CMS' proposal to use psychotherapy for crisis codes (90839, 90840) is a first step in providing financial support. However, **we urge CMS to first consider paying for the existing H2011 code used by Medicaid and to do so at rates that cover the cost of care.** There are limitations to psychotherapy for crisis codes in that they require the services be provided by a licensed provider that can bill independently. Much of this work is done by a multidisciplinary team that does not always include someone who can independently bill so this has the potential to create a barrier to care. The rate proposed does not fully cover the cost of care. The Substance Abuse and Mental Health Services Administration (SAMHSA)'s best practice-recommendations indicate the use of a two-person team. This is echoed in the American Rescue Plan Act of 2021 (ARPA),[5] CMS also references the use of teams in their memo to state Medicaid plans, and states, such as California,[6] have recognized care is provided in a team-based approach with at least a two-person team. The development of a modifier (or other coding option) could be a solution to ensure the payment captures the cost of the individuals involved in delivering the care. It is also important to recognize that services are set up to be operational 24/7. Finally, consideration should be given to waive

[5] ARPA
[6] BHIN-22-064

any cost-sharing requirements associated with crisis care thus removing a potential barrier and reducing the administrative burden of trying to recoup payment. Any adjustments to these codes to align with best practices should reflect the appropriate cost of care delivery. **APA encourages CMS to convene a group of interested stakeholders to consider payment and coverage policies that promote best practices/evidence-based models of crisis care.**

Intensive Outpatient Programs (IOP) (Section II.J.3)

Virtual delivery of partial hospitalization programs (PHP), a higher level of care, have been demonstrated throughout the COVID-19 PHE to be an effective way of delivering quality care to those with serious mental illness. It allowed people to access high-intensity services without incurring significant costs to travel or stay elsewhere, as well as allowing patients to keep working remotely while receiving services, without reductions in effectiveness or retention. In defining the IOP benefit, CMS has the opportunity to build on this success by allowing IOP to be delivered to patients in their home and community settings if the clinician determines that it would be the appropriate modality for the specific patient. At minimum, **APA encourages CMS to allow IOP in home and community-based settings as we gather data about the effectiveness of the intervention.**

Adjustments to Payment for Timed Behavioral Health Services (Section II.J.5)
Evaluation and Management (E/M) Visits (section II.F)

CMS has proposed to increase the work relative value units associated with select codes within the Psychiatry section of CPT including the stand-alone psychotherapy codes without making a corresponding adjustment to the add-on psychotherapy codes billed with evaluation and management services.

If, as stated in the Federal Register, CMS' intent with the increased valuation of the stand-alone psychotherapy codes is to "address the need for improvement in valuation for timed psychotherapy services based on the proposed valuation for the inherent complexity add-on code for office/outpatient E/M services," the simpler approach would be to add a G code to the Psychiatry section with an equivalent RVU to the G2211 code that could be used by qualified mental health professionals (i.e. psychologists and social workers) as an add-on to stand-alone psychotherapy, similar to the way the 90785 Interactive Complexity is used.

As currently proposed, while the G2211 value remains static at 0.33 RVU, the stand-alone psychotherapy code values increase by 0.63 RVUs for the 60-minute code (90837) by 2027, almost twice the value of the G2211 it is meant to compensate for. This approach would also reduce the budget neutrality impacts associated with the proposed increases to the stand-alone psychotherapy valuations, which would, if implemented as proposed, result in greater costs associated with their use than the G2211 equivalent.

We appreciate that CMS has recognized the limitations associated with the valuation of time-based services that must be performed directly by the clinician that offers no opportunity to become more efficient over time. We also agree with your statement in the 2012 final rule:

> "…we believe that the work involved in furnishing the psychotherapy add on CPT codes is very similar to the work of furnishing the stand-alone psychotherapy CPT codes…"

The work itself is the same regardless of the professional degree held by the clinician, with the same constraints due to the time-based nature of the codes and the fact that the clinician - and not their clinical staff - must provide the care.

As we stated in our letter to CMS in 2021, when a similar proposal was made and finalized, CMS is effectively eradicating the relativity in the work RVUs by increasing the work values for stand-alone psychotherapy codes and not doing the same for the corresponding add-on psychotherapy codes. In 2021 that resulted in a relativity gap of 13-32% between the identically timed add-on and stand-alone psychotherapy codes. By 2027 under this proposal that gap widens to between 35 and 58% difference in values. (See table below)

CPT1/HCPCS	DESCRIPTION	Total	CY 2014-2020 Work RVU	Differential btwn standalone & add-on (2014-2020)	CY 2021-2023 Work RVU	Differential btwn standalone & add-on (2021-2023)	Fully Transitioned Work RVU (2027)	Fully Transitioned Differential btwn standalone & add-on (2023-2027)
90832	Psytx w pt 30 minutes	2,184,946	1.5		1.7		2.02	
90833	Psytx w pt w e/m 30 min	1,367,087	1.5	0	1.5	13%	1.5	35%
90834	Psytx w pt 45 minutes	4,201,662	2		2.24		2.67	
90836	Psytx w pt w e/m 45 min	454,175	1.9	5%	1.9	18%	1.9	41%
90837	Psytx w pt 60 minutes	6,075,835	3		3.31		3.94	
90838	Psytx w pt w e/m 60 min	95,661	2.5	20%	2.5	32%	2.5	58%

Implementation of the proposal will further exacerbate the lack of pay-parity. When fully implemented, the proposed work RVU adjustments will mean that the work values for non-physician clinicians will be higher for a 60-minute psychotherapy visit than for a psychiatrist who provides both 60-minutes of psychotherapy and an E/M service with low or moderate complexity.

This proposal, if approved as written, will have the unintended consequence of devaluing the work of psychiatrists when compared to psychologists, social workers, and other mental health professionals, thereby further discouraging psychiatrists from choosing to take Medicare, and at the same time reducing access for patients to what has been shown to be one of the most effective treatments – combined psychotherapy and medication management. You have stated a goal of increasing participation by psychiatrists in Medicare. This proposal, without modification, will have the unintended effect of doing the opposite. **APA urges CMS to finalize an equivalent increase for all the time-based psychotherapy services including the add-on psychotherapy codes.**

G2211 Complexity add-on code (Section II.F)

APA supports the use of the G2211 visit complexity code as it recognizes important work that occurs when providing care to Medicare patients with mental health disorders, many of whom are chronically ill with co-morbid medical conditions or are younger and disabled. This payment would be a start to supporting additional work that is required to ensure patients are stable and or improving. However, this is not psychotherapy, and the rationale for adding visit complexity to stand-alone psychotherapy should not be conflated with the value of psychotherapy, with the result of further widening the gap in valuation between a psychotherapy service performed as stand-alone vs as an add on to E/M work.

Updates to the Payment Rate for the PFS Substance Use Disorder (SUD) bundle (HCPCS codes G2086-G2088) (Section II.J.7)
APA supports CMS' proposal to increase payments for services associated with the treatment of substance use disorders.

Comment Solicitation on Expanding Access to Behavioral Health Services (Section II.J.7)
We appreciate CMS' ongoing interest in expanding access to behavioral health services for Medicare beneficiaries.

Behavioral Health Integration Services including CoCM
Psychiatric Collaborative Care (CoCM)
CMS has an opportunity to capitalize on efforts by others to increase access to high quality care for mental health and substance use disorders through **increased support for the implementation of the Psychiatric Collaborative Care Model (CoCM).** There are currently a number of initiatives underway in multiple states including North Carolina, Michigan, Texas, NY and others that offer enhanced payments, and/or technical support to assist primary care practices in establishing and maintaining this evidence-based model. CoCM can help CMS reach its goal of managing costs by reducing other more costly services associated with un/undertreated mental illness and by improving beneficiary satisfaction and quality of life.[7,8] It is in CMS' best interest to support this model by enabling additional implementation support, decreasing unnecessary barriers to adoption, and ensuring the delivery is fairly reimbursed as it is a high value service with a strong evidence-base that is currently, vastly underutilized. Just like there has been recent evidence around the success of the COVID-19 policies to support access to buprenorphine,[9,10] a focus on policy to support access to the Collaborative Care model is critical to increasing the prevalence of this important model of care.

We urge CMS to support technical assistance and increased payments for CoCM as the uptake of the CoCM codes within Medicare continues to be limited. Implementation of CoCM requires a change in practice for primary care practices both in terms of upfront financial investment for hiring, training, and registry creation as well an investment of staff time to develop and update clinical and billing workflows. We recommend CMS fund technical assistance and implementation support for at least the first three years of implementation. There is currently legislation in Congress that seeks to direct CMS to increase the current Medicare payment for each code in the CoCM family of codes by a minimum of 75% for the first year, 50% for the second year and 25% for the third year to help practices cover these upfront costs.

Other payers are recognizing the need to increase the valuation to sustain this clinically efficacious and cost-effective model. There are a growing number of commercial payers and state **Medicaid plans paying**

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3810022/
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9803502/
[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7833481/
[10] https://doi.org/10.1186/s13011-022-00483-1

CoCM at an enhanced rate because they recognize the clinical and financial value of implementing the model. A recent claims analysis by AHIP found that the use of the CoCM and general BHI codes and payments for those services have increased since 2018 with commercial rates averaging 150% of Medicare and several state Medicaid plans are paying at least 120% of Medicare rates. **We urge CMS to value the services at a rate that is more reflective of the current market's cost to deliver**, recognizing that the long-term savings through earlier identification and treatment will be worth the upfront financial investment.

We recommend CMS increase the work RVUs associated with the delivery of CoCM. The current work RVUs assigned to the CoCM codes contribute to the undervaluation of the services. The original valuation was based on an underestimate of the time spent by the psychiatric consultant over the course of the month reviewing the patient's case, contributing to the development of the patient's care plan, and answering questions and concerns from the behavioral health care manager and the primary care clinician. As with similar proposals within this rule, CMS should also recognize work similar to the complexity add-on code (G2211) is performed as part of the model by either increasing the valuation of the CoCM codes or allowing it to be used as an add-on to the service.

We recommend CMS ask the Correct Coding Initiative (CCI) Contractor to remove the MUE edits assigned to the 99494 CoCM add-on code for additional time. There are instances, particularly in the first month, which require additional time beyond what is captured in the billing of the base code and two add-on services. Additional time may also be required when providing CoCM services to patients (geriatric, cognitively impaired, pediatric, etc.) with caregivers and others involved in their care increased time will be necessary for coordination with multiple stakeholders including, family/caregivers, teachers, and school counselors. This loss of revenue associated with unreimbursed care management due to the arbitrary limits has financial implications for the practice.

CMS can increase efficiency and further reduce uncompensated care by clinical staff to obtain patient consent to participate in CoCM under general supervision of the treating physician. The care manager can do this more efficiently, as part of the patient education and engagement that is intrinsic to their role. Once consented there should be no need to re-consent a patient during an episode of care as consent should be tied to inclusion in the program within the practice and not to the identified treating clinician.

We urge CMS to ensure appropriate payment mechanisms are in place for all relevant practice settings including hospital-based outpatient clinics. Academic medical centers and other hospital systems with outpatient provider departments are the most well positioned settings to implement collaborative care. We do not believe it was CMS' intent to NOT provide CoCM in those settings, however we understand there are barriers to billing, including the interpretation of "incident to" rules by compliance teams which has halted implementation of the model.

CMS can increase the use of CoCM services in FQHC/RHC practices by:

- Allowing FQHCs and RHCs to bill based on the time rules as defined in CPT. There is confusion and hesitancy to adopt the model in FQHCs and RHCs because of the lack of direction in how to bill for CoCM delivery. Most payers, including many Medicaid plans, use the CPT codes to bill for

CoCM services and we urge CMS to allow and encourage FQHCs and RHCs to use these same CPT codes to bill. Consistency across payers will reduce the administrative burdens and potential errors that occur when clinics are required to adhere to vastly different billing workflows for what is likely a small subset of patients.

- Allowing FQHC/RHCs to collect their encounter rate or AIR for the monthly billing to incentivize these safety-net practices to adopt evidence-based behavioral health integration services.

In addition, CoCM services often include crisis services. **New HCPCs codes specific to CoCM crisis services should be created, with higher rates given the intensity of the services.**

Measurement-Based Care

APA recommends CMS also incentivize adoption of Measurement-Based Care (MBC) both in primary and specialty care by providing financial support and technical assistance. MBC has been shown to be effective in improving outcomes and patient and clinician satisfaction.[11] In a 2022 report to Congress, SAMHSA's Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC) highlighted the positive effects of MBC; accrediting organizations and payers have also begun to recognize its value. MBC increases screening and can improve early identification and prevention and is more effective in improving outcomes than screening alone.

As with CoCM, clinicians in both primary care and specialty care have been slow to adopt MBC. A 2020 JAMA Psychiatry article (Lewis et al) summarized several barriers faced by individual clinicians and organizations.[12] Implementation will require stakeholder buy-in to adapt to a change in practice.[13] Incentives, such as coverage of CPT® codes *99484 and G0323 (Care management services for behavioral health conditions*) provide a starting point however will not fully account for the costs to implement this model of care. The current valuation does little to incentivize MBC. As with CoCM, providing implementation funding and support through technical assistance in addition to reimbursement mechanisms that incentivize change could reduce the barriers to adoption. This is one way all primary care and specialty care practices can improve outcomes for their patients suffering from MH/SUD.

Increasing Medicare Participation by Psychiatrists

It is widely known there has been and continues to be an ongoing psychiatrist workforce shortage exacerbated by the COVID-19 public health emergency. HRSA projections indicate that even with the increase in the number of psychiatric nurse practitioners and psychiatric physician assistants entering the workforce, this will not fully offset the projected decline in the numbers of psychiatrists providing clinical care.[14] It is currently difficult to fill openings for psychiatrists. As a result, hospitals must limit admissions, appointments for outpatient care are delayed, and mental health practitioner burnout continues to

[11] https://mmhpi.org/wp-content/uploads/2021/03/MBC_Report_Final.pdf
[12] https://pubmed.ncbi.nlm.nih.gov/30566197/
[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6996080/
[14] https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/bh-workforce-projections-fact-sheet.pdf

increase. Unfortunately, the numbers are not in CMS' favor. While a recent MedPAC report noted that sixty percent of psychiatrists accept Medicare, it went on to state that those mental health clinicians that do see Medicare patients, "psychiatrists see the most Fee for Service (FFS) beneficiaries of all behavioral health clinicians, both in aggregate (over 2 million) and per provider (87 FFS beneficiaries per psychiatrist, on average)."[15]

Psychiatrists that don't accept Medicare cite, among other things, reimbursement rates that are significantly lower than current market rates, administrative burdens, and inability to meet the needs (i.e., care management activities, activities related to social determinants of health) of Medicare patients who are older and/or disabled. Given the competitive market, what Medicare offers is often not enough to encourage psychiatrists to participate. Reimbursement is not just the difference in payment between Medicare and self-pay rates but also about the inability to sustain a practice that is heavily weighted to Medicare patients. The fluctuation of Medicare rates given the annual changes in the conversion factor and the impact of bonuses or more likely payment penalties under MIPS, make it difficult for psychiatrists, especially geriatric psychiatrists, to stay in business. The overall rates must be increased to even maintain the numbers of participating psychiatrists.

Participation can be increased through several pathways:

- New residency training and new pathways for Medicare providers
- Incentivizing psychiatrists not to opt out of Medicare
- Further incentivize existing Medicare providers to expand their Medicare population within their practice

APA encourages CMS to start implementing incentives and education about Medicare Participation during residency training and continuing throughout their career. The Medicare population is different from commercial insurance or cash pay populations. There are additional medical complexities that providers need to be trained to treat including dual eligibles and elderly patients with comorbid conditions. Many times, coordination of additional care and case management is needed, which is currently not feasible in solo and small practices. There must be new incentives and pathways for clinicians to treat Medicare beneficiaries in their training and work settings.

For many psychiatrists, it's not just Medicare vs. commercial insurance – it's insurance participation as a whole vs. cash-pay. APA has heard from some members that cash-pay rates in large cities (e.g., New York, Boston, San Francisco) can be as high as $1000 per visit. While psychiatrists would like to work with the Medicare population, they (if in solo practice) and their employers need to be able to balance their budget with the mix of patients that pay at different rates, which requires CMS to implement creative incentives to overcome the disparity in cash-pay rates in large markets. These strategies could include easier and

[15] https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch6_MedPAC_Report_To_Congress_SEC.pdf

faster reimbursement, support with health-related social needs of their patients, loan repayment programs separate from the national health service corps, and technology and infrastructural support.
A loan repayment incentive could look something like providing a certain payment for a specific number of years an early career psychiatrist treats a percentage of Medicare patients. Another potential incentive could be providers earning reimbursement for liability insurance costs by taking a percentage of Medicare patients, similar to Veterans Affairs practitioners who do not pay their own malpractice insurance.

CMS recognized earlier in this rule the limitations associated with the valuation of time-based services that must be performed directly by the clinician where there is no opportunity to become more efficient over time. **The solution (to increase the stand-alone psychotherapy codes without a corresponding increase to the add-on codes) as currently proposed would be a disincentive to psychiatrists and runs counter to the policy objective of increasing participation.**

As noted above, the differential between Medicare payments and the marketplace, including some commercial in network rates as well as private pay can be significant, disincentivizing psychiatrists from participating. There is some pressure in smaller groups not to participate because the rate differential is so great. Low rates for Medicare and Medicaid also compromise care for those who are dually eligible, some of our most vulnerable Medicare beneficiaries. Given the medical complexities of patients covered by Medicare, dual eligible (young patient with schizophrenia) or elderly patients with comorbid conditions (frail, acuity, etc.), CMS should consider risk adjustment to incent collaboration and care across other care providers and improved reimbursement for care management and coordination.

We also note that psychiatry has a relatively high rate of clinicians without robust technology infrastructure, including EHRs and electronic billing platforms, due in part to a higher rate than other specialties of working in community-based settings and a higher rate of independently practicing physicians. Federal agencies can provide and support technical assistance to psychiatrists in obtaining and using infrastructure that enables participation in Medicare, data sharing and integration, and continuity of care as a mechanism for increasing access to and coverage of psychiatric services.

For those who are already participating, CMS should incentivize practices to expand the number of beneficiaries the practice accepts. This includes change management solutions to help psychiatrists that accept Medicare in their private practice to increase the number of Medicare patients they serve in their practice and aligning Medicare rates to commercial insurance to allow smaller practices to increase the number of beneficiaries served.

Separate coding and payment for interventions initiated or furnished in the emergency department or other crisis setting for patients with suicidality or at risk of suicide

APA supports payment for evidence-based safety planning interventions both within emergency departments (ED) and crisis encounters, the focus of our comments here, as well as in the ambulatory care setting.

The Safety Planning Intervention (SPI), which involves a member of the clinical staff working collaboratively with the patient to build a personalized safety plan that is documented and includes warning sign identification, reducing access to lethal means (e.g., firearms, medicines), problem-solving/coping strategies, and identification of emergency contacts,[16] is effective and critical in suicide prevention as echoed in clinical practice guidelines from the Department of Veterans Affairs/Department of Defense,[17] recommendations from the Joint Commission,[18] and the National Action Alliance for Suicide Prevention.[19] In fact, the SPI has been found to be clinically useful and feasible by both suicidal individuals and clinicians and is associated with reduction in suicidal behaviors. Individuals with suicidal ideation and behaviors also report that the SSP helps them maintain their safety and increases the likelihood of them remaining in care.[20,21] The intervention is brief, easy to learn and administer, and is work that can be performed by a member of the clinical staff working in collaboration with the patient. In combination with the Post-Discharge Telephonic Follow-up Contacts, SPI has been found to be effective and fairly cost-effective.[22,23] Neither intervention is widely implemented in the ED setting, with likely more limited implementation in other crisis settings.

APA supports the development of adequate payment mechanisms to cover the cost of furnishing SPI, and the post-discharge telephonic follow-up contacts, which could incentivize a more widespread implementation of the intervention. Based on feedback we have received from clinicians and hospitals, the current mechanisms (professional services under Part B, and facility costs under Part A) are not sufficient to support the intervention. SPI is typically furnished by a variety of clinical staff, including peers, with appropriate training and supervision. While licensed practitioners can also furnish SPI effectively, it is typically not efficient for them to do so in settings where other suitable staff could be used.

Enabling effective and efficient implementation of SPI for ED patients when indicated likely will require a new designated payment mechanism. Reflecting research and practice experience, this mechanism should enable SPI to be furnished to ED patients by staff who are not themselves licensed practitioners, with appropriate training and supervision.

We would like to avoid the problems associated with a different ED service, Screening/Assessment, brief intervention and referral treatment (SBIRT), for patients with substance misuse, which has had limited uptake in the ED and hospital setting in large part due to the fact Medicare requires the services to be performed and billed by a licensed professional rather than by clinical staff. The SBIRT model was developed and tested in research to be furnished using clinical staff (who are not licensed) working

[16] https://pubmed.ncbi.nlm.nih.gov/26828397/
[17] https://www.healthquality.va.gov/guidelines/MH/srb/VADoDSuicideRiskFullCPGFinal5088212019.pdf
[18] https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/suicide-prevention/suicide_prevention_resources_ep6_npsg150101.pdf
[19] https://theactionalliance.org/sites/default/files/action_alliance_recommended_standard_care_final.pdf
[20] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5829088/
[21] https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2687370
[22] https://pubmed.ncbi.nlm.nih.gov/28456130/
[23] https://pubmed.ncbi.nlm.nih.gov/31451063/

incident to and under the general supervision of a licensed practitioner. We understand from our emergency room colleagues that this requirement is a substantial barrier to widespread implementation of SBIRT for ED patients because most EDs are not adequately staffed for licensed practitioners to furnish SBIRT at the current valuation.

SPI is also indicated for patients identified with elevated suicide risk in other care settings, including inpatient care, general medical and behavioral health specialty outpatient care, and crisis care settings. **APA urges CMS to consider the adequacy of current and potential new payment mechanisms to support furnishing SPI when indicated, for each relevant care setting, e.g., hospitalization for medical reasons (i.e., self-harm injuries), via the Inpatient Prospective Payment System (PPS) or other mechanism; psychiatric hospitalization, via the Inpatient Psychiatric Facility PPS or other mechanism; and ambulatory care, via the Physician Fee Schedule.**

While it may be feasible to implement adequate payment for SPI in EDs (and other relevant care settings) without implementing a designated billing code for SPI in HCPCS and/or CPT, we expect that implementing such a code would have important benefits. Most immediately, with a designated code, the essential service elements of evidence-based SPI (i.e., within-encounter SPI, plus at least one follow-up telephone contact with patients within a few days after discharge, to reinforce and potentially refine the elements of the patient's safety plan) can be built into the requirements for billing, which will likely increase the fidelity of SPI furnished in real-world care.

A designated code for SPI would also make it significantly easier to document that SPI was furnished, including in quality reporting and value-based payment programs. Absent a designated HCPCS or CPT billing code for SPI, documenting performance on relevant measures – specifically, whether a patient in the measure denominator meets the numerator criteria of having received SPI – is not possible via claims data, nor even via electronic health record data in any standard way. A designated code for SPI would address this, thereby increasing the utility, and reducing the burden, of using this quality measure in all relevant care settings.

The Post-discharge Telephonic Follow-up Contacts Intervention (FCI) involves furnishing a series of telephone calls proactively over a number of months after an individual has been identified with suicide risk. The contacts express concern for the well-being of the individual, review suicide risk, review safety plan use, clarify patient values and goals, support problem solving, and facilitate help-seeking and treatment engagement. FCI commonly involves 6-8 contacts over a follow-up period of 6-12 months after an index event. Contacts can be coordinated and furnished in various ways, e.g., by the provider or facility where the patient was identified, from a central point determined by a health system or health plan, or by a partner organization such as a crisis call center. Staffing can be flexible – with appropriate training, supervision, and confidentiality protections – including via licensed behavioral health practitioners, other types of clinical staff, crisis call center staff, and potentially others.

Multiple trials have found FCI to reduce suicide attempts and deaths, including interventions involving telephone contacts alone; or, in the recent NIMH-funded ED-SAFE trial, and in a Veterans Administration

study for ED patients with suicide risk, in combination with SPI. Indeed, FCI is among very few interventions that have been shown to improve these outcomes. Based on such evidence, most of the bulleted policy documents cited above, in the subsection on SPI, also recommend providing FCI after discharge for ED patients identified with suicide risk.

Moreover, economic evaluation of FCI for suicide prevention has found this intervention to have very favorable cost-effectiveness, alone or in combination with SPI. However, furnishing FCI does incur direct costs, vs. treatment without FCI – and so the availability of adequate payment mechanisms under public and private insurance is likely a necessary condition for widespread implementation.

FCI can be furnished effectively by a variety of staff, including licensed practitioners, other clinical staff, crisis call center staff, and others, with appropriate training and supervision. In ED-SAFE, the intervention included up to 7 brief (10- to 20-minute) telephone calls to the participant and up to 4 calls to a "significant other" (SO) identified by the participant, if available, in the 52 weeks following the index ED visit; calls were furnished by several types of staff, including PhD psychologists, psychology fellows, and a masters-level counselor, and they focused on identifying suicide risk factors, clarifying values and goals, safety and future planning, facilitating treatment engagement/adherence, and facilitating patient-SO problem-solving.

Patients qualify for FCI based on being discharged from ED or hospital after being identified with elevated suicide risk. Thus, one logistical requirement for furnishing FCI when indicated is awareness that a patient has had a qualifying event. Then, there needs to be an assumption, or assignment, of responsibility for furnishing FCI by some appropriate entity. As we note above, there is substantial flexibility in the entity that furnishes FCI, e.g., the ED or hospital itself; another part of the ED/hospital's parent health system (when applicable); a specialty FCI vendor, analogous to the centralized call center that furnished FCI to patients from the eight EDs that enrolled participants in the ED-SAFE trial; a designated crisis call center, as used in the pilot FCI program in Colorado in which multiple EDs in Colorado have partnered with Colorado's crisis call center to furnish FCI to adult ED patients identified with suicide who are discharged (vs. being hospitalized); or others.

We are not aware of existing payment mechanisms that support furnishing FCI after ED (or hospital) discharge when indicated, under Medicare or other public or private insurance. By design, FCI is furnished to patients in the community, across multiple months after discharge. FCI addresses a kind of care transition, for which CMS has introduced various kinds of new payment in recent years, and we do see some overlap in intent and service elements with some existing care transition services. To our knowledge, however, none of these aligns with the details of evidence-based FCI – including that FCI requires multiple contacts, across months – such that it provides adequate support for furnishing FCI where indicated.

We note that certain health care quality measures, particularly those focused on receipt of outpatient behavioral health care within 7 and 30 days of discharge from psychiatric inpatient care or after a behavioral-health-related ED visit, may help incentivize at least *some* proactive follow-up contact with

patients – but on a much more limited basis, and for clinically different purposes, than FCI. The same is true for the types of proactive outreach that many hospitals furnish to reduce the risk of readmission, in response to CMS policies under which hospitals are at risk for the cost of readmission under certain circumstances. (Also, to our knowledge, there are no such policies for patients discharged from the ED, neither for physical nor behavioral health issues.)

While it may be feasible to implement adequate payment for FCI for patients after ED (or hospital) discharge without implementing a designated billing code for FCI in HCPCS and/or CPT, we expect that implementing such a code would have important benefits. In particular, as with SPI, a designated code would be designed to embed the essential service elements of evidence-based FCI as requirements for billing, which will likely increase the fidelity of SPI furnished in real-world care. In this regard, we note particularly that FCI requires multiple contacts over time, and the effectiveness of furnishing single follow-up contacts has not been established; thus, defining FCI as a bundled/episode-based service may help enable furnishing FCI effectively.

As we have described, we view wider implementation of SPI and post-discharge follow-up contacts as clinical and public health priorities in their own right. We also expect that wider implementation of these interventions will benefit other aspects of suicide prevention, particularly by facilitating wider screening to improve detection of suicide risk in ED and hospital patients.

Finally, we note that adoption of SPI and FCI for suicide prevention would additionally be enhanced if their payment mechanisms could be implemented without requirements for directly-associated patient cost-sharing – in any care setting, but most importantly in ED and inpatient care. We are not aware of any current or prior implementation of either of these interventions that has required patient cost-sharing; we are concerned that some patients will decline consent to receive either or both of these interventions – which are designed to be furnished proactively by the health system – if patient cost-sharing is required. Zero patient cost-sharing would also streamline service delivery, because staff would not need to obtain and document active patient consent for these interventions.

Provider address

During the COVID-19 PHE, CMS permitted practitioners to list their practice address, rather than home address, on form 1500 when providing telehealth from home. CMS guidance currently only maintains this flexibility through CY 2023. Reverting to requiring reporting of the physical location of the clinician poses a safety risk to clinicians. CMS' preexisting requirement that practitioners report their physical location at the time the prescription is written – even if that is their home address during a telehealth encounter – is unnecessary and potentially dangerous. We have heard from APA members who have experienced safety issues due to personal information getting into the hands of a few individuals seeking to harm the practitioner. **This poses a retention risk for Medicare participation among psychiatrists, and we recommend that CMS permanently allow practitioners to list their practice address rather than home address.**

Request for Information on Digital Therapies, such as, but not limited to, digital Cognitive Behavioral Therapy (Section II.J.8)

Due to greater accessibility, flexibility, and convenience for patients than in-office care, mobile patient-driven mental health and wellness support and self-management tools are an appealing approach to low 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.

First, we offer clarification regarding the framing of this request for information. While the RFI refers to the codification of remote therapeutic *monitoring* for cognitive behavioral therapy (CBT) – 989X6 – the RFI also asks about digital therapeutic *interventions.* As currently designed, 989X6 is a code for a device intended to use technology to collect patient-reported outcome measures and track other behaviors (e.g., medication adherence) that can indicate therapeutic progress, not a code for the delivery of CBT. Digital CBT describes a class of tools in which CBT is delivered through software, either with or without the addition of a clinician guiding and supporting the patient. While monitoring is an important part of the therapeutic process and can help inform therapeutic steps, monitoring is distinct from intervention.

Next, while we recognize the incorporation of the definition of a "device" per section 201(h) of the Federal Food, Drug and Cosmetic Act (FFDCA), we note that there is no definition of a "digital therapeutic" propagated by either CMS or FDA. Accordingly, it is difficult to determine which clinical use cases and current technologies may fall under these definitions. The Digital Therapeutics Alliance defines digital therapeutics as "health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health," but there are multiple issues with broadly adopting this definition: (1) there is a wide and unpredictable spectrum of standards that can be applied to understand if an item has "demonstrable positive health impact;" (2) inclusion of hardware as a component of digital therapeutics varies; and (3) there are items that would be colloquially considered digital mental health therapeutics on the FDA Breakthrough Device list that lack generalizable data indicating their effectiveness (e.g., a device with only 63 patients studied). Most positive studies of CBT software are not conducted with scientific rigor, including lacking control groups. **FDA and CMS must collaborate on a clear, practical definition of digital therapeutics and apply a rigorous standard of evidence of safety and effectiveness prior to codifying reimbursement for these products.**

Digital therapeutics should not replace evidence-based clinical care. Safety and effectiveness for mental health devices should not be premised on a device not causing physiological harm or physical danger: rather, there is significant risk in leading a person with mental illness to believe that they are receiving an effective treatment when they may not be. In general, digital therapeutics have not been robustly tested and do not meet an adequate threshold of evidence of effectiveness and safety to be applied to patients without significant clinician oversight. Lack of intended outcomes associated with using the device could lead to negative patient beliefs and behaviors including fatalism, or the belief that nothing will help them in recovering from mental illness; lack of trust in clinicians; and avoidance of future care. Some may even cause harm: a 2022 study by Kaiser Permanente of nearly 19,000 patients, published in JAMA, showed

how one digital intervention led to an increase in suicidal ideation in patients.[24] In patients with serious mental illness, outcomes of ineffective treatment are possible including death due to overdose or suicide.

Finally, while digital interventions can mitigate many elements of inequity including lack of access to transportation, paid time off work, childcare, and other health-related social needs, there are structural equity considerations in the application of digital interventions as well. **Key elements of digital inclusion include 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).**

Responses to each element of the RFI are below:

How do practitioners determine which patients might be best served by digital therapeutics? How do practitioners monitor the effectiveness of prescribed interventions, such as, but not limited to, for their patients on an ongoing basis once the intervention has begun?

Considering the highly variable market, features, definitions, and assessment frameworks of apps in combination with the complex needs, preferences, and capabilities of patients, there is not one set of criteria that can be used to recommend or "prescribe" a specific digital intervention for a specific patient. **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 need and should not replace clinical care.** APA's open-access, online *Digital Mental Health 101: What Clinicians Need to Know When Getting Started* resource document includes key considerations for clinicians to assess patient readiness and appropriateness for digital interventions, including hardware considerations, software and connectivity considerations, and digital literacy.[25] We then provide guidance on clinical applications and considerations within specific patient populations and settings, overviewing use of mobile applications in outpatient, inpatient, integrated care, child and adolescent, geriatric, serious mental illness, emergency and crisis, peer support, dual diagnosis, and psychiatric nursing settings.

Because digital health apps are often marketed and deployed directly to patients, the APA convened a group of experts to evaluate the effectiveness and safety of digital mental health interventions. This group developed the APA's App Advisor, an open-access, online framework for evaluating an app's appropriateness for a specific patient.[26] APA's App Evaluation Model employs a hierarchical assessment structure to assist clinicians and patients in understanding the appropriateness and safety of using a mental health app. The model recognizes that many app-based interventions are untested according to typical clinical standards, requiring a more comprehensive evaluation by potential users to match a digital intervention to a clinical objective.

[24] Effect of Offering Care Management or Online Dialectical Behavior Therapy Skills Training vs Usual Care on Self-harm Among Adult Outpatients With Suicidal Ideation: A Randomized Clinical Trial.
[25] Digital Mental Health 101: What Clinicians Need to Know When Getting Started.
[26] APA App Evaluation Model.

Accordingly, the model recognizes the central role that clinicians can play in helping patients access safe and appropriate technologies. The APA's App Advisor does not recommend or rate apps but rather provides a framework for assessing them on a case-by-case basis. The "clinical foundation" element of the assessment helps users evaluate the potential benefits of the app, including that it is reasonable and not harmful ("face validity"), does what it claims to do, and is based on a clinical foundation relevant to the intended purpose. Because of the lack of credible high-quality scientific evidence (e.g., digital placebo-controlled studies), the framework cannot yet ask clinicians to assess the clinical effectiveness of apps. **APA encourages CMS to consider using a similar framework in assessing the usage of apps in the Medicare population.**

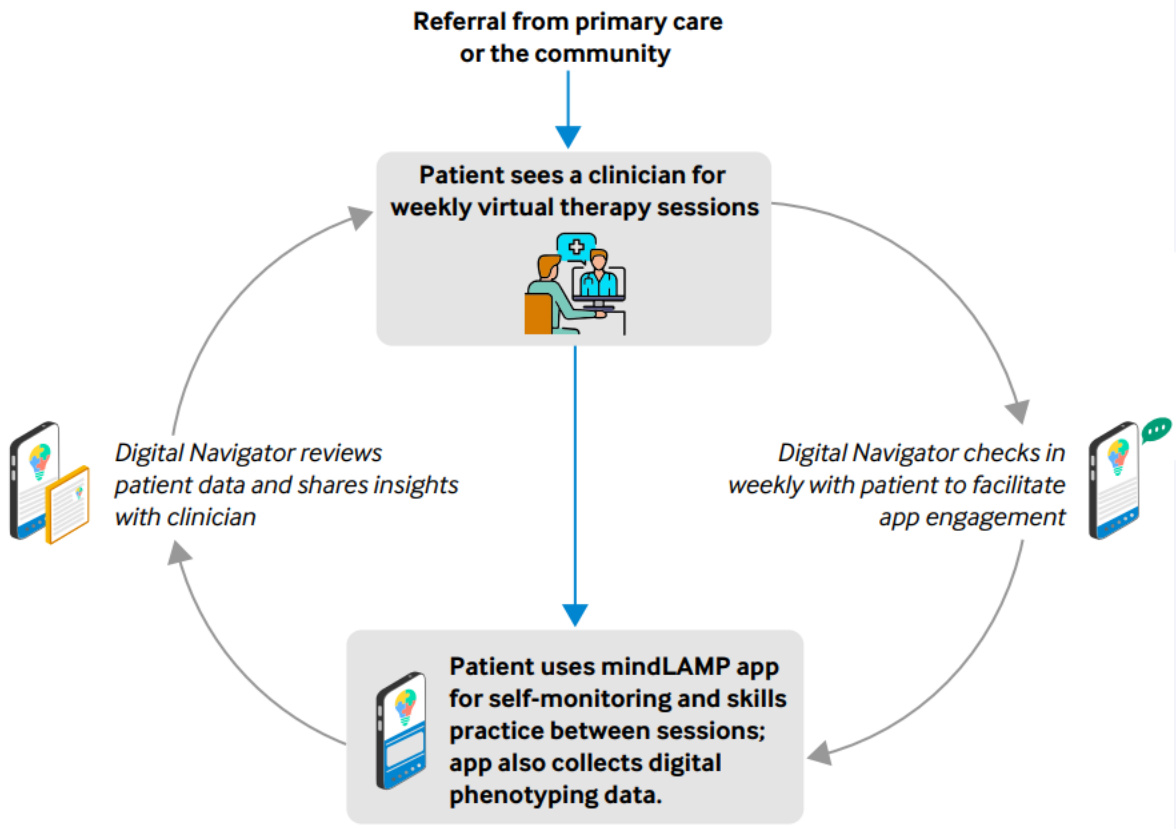
The majority of research-supported psychotherapies, including the traditional CBT approaches on which digital CBT approaches are based, are disorder-specific and were developed for use with individuals with a diagnosed mental illness and a clinically-indicated level of severity. It is unclear how efficacious digital CBT is at this time. There is, accordingly, no empirical basis for digital CBT interventions used in the absence of clinical assessment and intervention.

We seek comment and real-life examples where digital cognitive behavioral therapy or other digital enabled therapy services are used by clinicians, and how the technology is imbedded in various practice models. For example, how is the patient evaluated and/or how is the treating clinician involved in the services received when the patient participates in digital cognitive behavioral therapy?

APA's Digital Mental Health 101 resource includes the following guidance for clinicians incorporating digital health into their practice: "Within patient-clinician encounters, it is important to allow clinicians (or other members of the care team) time to, first, learn how to use the technology themselves, and second, teach patients how to use apps. Such training can occur before, during, and after appointments. Beyond clinical time for teaching, monitoring app usage and data is important. If the app provides patient-generated health data (PGHD) that is relayed 24/7 to the health system, then clinicians must be given sufficient time to understand, grasp, and take action on any data provided. by the app. This will require additional staff resources.

Below is an illustration of a clinical workflow incorporating app-based supports: [27]

[27] The Digital Clinic: An Innovative Mental Health Care Delivery Model Utilizing Hybrid Synchronous and Asynchronous Treatment.



Source: The authors
NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

What standards have interested parties developed or consulted to ensure the physical safety and privacy of beneficiaries utilizing digital cognitive behavioral therapy (CBT) and/or other digital therapeutics for behavioral health?

APA's App Evaluation Model incorporates the privacy and security of an app as the foundational step in evaluating its appropriateness for clinical use. The App Evaluation Model notes that "apps present some unique risks that may often be overlooked. Risks may include data costs associated with app use (i.e., depending on the contracted data plan with the wireless provider), social profiling, loss of insurance benefits or insurability—all of which are associated with privacy and security." The APA's App Advisor criteria for privacy and security are:

1. Is there a transparent privacy policy that is clear and accessible before use?
2. Does the app declare data use and purpose?
3. Does the app describe use of PHI?
    - Deidentified vs. anonymous?
4. Can you opt out of data collection or delete data?
5. Are data maintained in the device or on the web?
6. Does the app explain security systems used?
7. Does the app collect, use, and/or transmit sensitive data? If yes, does it claim to do so securely?

8. What third parties does the app share data with?
9. If appropriate, is the app equipped to respond to potential harms or safety concerns?

Many behavioral health-related apps are not HIPAA-covered entities and, accordingly, are held to very minimal standards of data privacy. In recognition of this regulatory grey area and of the fact that many patients and clinicians may believe data in these apps are being protected when they are not, APA encourages broader enforcement of the protection of non-HIPAA-covered health-related data by the FTC. Collaboration between HHS/OCR, CMS, FTC, and informaticists may be valuable to operationalize definitions of health-related data and generate additional regulatory frameworks to protect patients in digital environments.

What are effective models for distribution/delivery of digital therapeutics, such as prescription digital mental health therapy products to patients? What best practices exist to ensure that patients have the necessary support and training to use applications effectively?

There is no evidence linking higher-cost digital health interventions with clinical effectiveness; in fact, "No correlation was observed between clinical robustness [of digital health startups] … and total funding (r2=0.08)."[28] It is essential that approval and coverage of these tools be premised on a high standard of evidence. Education programs for both clinicians and patients can help all parties make more informed choices on what they wish to use based on relevant criteria.

As APA's Digital Mental Health 101 resource notes, "onboarding patients can help them understand and use apps to the fullest and enhance engagement. Among three approaches for onboarding, clinicians can recommend the app, perform hands-on exercises in the clinic, or perform onboarding outside the clinical encounter:

(1) In *prescribing an app*, a clinician can meet face-to-face with a patient, explaining to them the features of the app and explaining how it will help them. Helping patients understand why the app is important for their care is critical toward ensuring higher rates of engagement with that app. Outlining the safety plan (if any) around the app and when (or if) data will be reviewed are also important and should be documented. For apps offered as self-help, expectations should be fully understood by all parties.
(2) *Hands-on exercises* involve using the digital app with a patient to guide them through exercises in the clinic and then discuss their progress afterwards. This may not always be feasible and can also be accomplished through use of support staff or digital navigators as one of many examples.
(3) Finally, *onboarding outside the clinical encounter* can occur by clinicians who conduct outreach to patients and guide them through their needs. For instance, this occurs within the Department of Veterans Affairs (VA) when onboarding patients to the VA Video Connect app and health devices through the Digital Divide consult.

[28] Assessing the Clinical Robustness of Digital Health Startups: Cross-sectional Observational Analysis.

By following an onboarding process, clinicians can help patients moderate expectations, reduce anxiety, and overcome failure fears." Further, "Onboarding and change management processes need to be structured for the user's technological literacy. Engagement with an app may be influenced by disparities in income, education, and access to telecommunications infrastructure. The user's own mental health history may influence their engagement, confidence, and familiarity with the internet and connected devices. Adequate support should go beyond the app to include assistance with basic technology functions such as accessibility, battery charging, operating system issues, and device security."

What practitioners and auxiliary staff are involved in furnishing RPM and RTM services, including training patients on its use, and to what extent is additional training or supervision of auxiliary staff necessary to provide an appropriate for and/or recommended standard of care in the delivery of these services?

Personnel with specialized expertise can teach patients how to use a remote monitoring tool, interpret and apply any data derived from the device, and teach patients how to use any other digital interventions including CBT. APA's Digital Mental Health 101 resource addresses specific personnel that can support patients in accessing digital health services: "One example [of personnel to support patient use of digital health tools] piloted at Beth Israel Deaconess Medical Center (BIDMC), Easter Seals of Greater Houston, and the Greater Manchester Mental Health Trust (UK) is to train peer specialists as digital navigators and expert technology teachers. Other related roles include a mental health technology specialist able to offer similar benefits. These digital navigators can offer programs like Digital Outreach for Obtaining Resources and Skills (DOORS)—a series of pragmatic and interactive lessons designed to develop new functional skills for accessing and utilizing the promise of digital health. Other grassroots efforts geared beyond mental health have also emerged, and many more will meet this urgent need."

The large volume of data that would be generated by additional RTM/RPM activities would require personnel to recognize any patterns in the data, to assess revisions to the care plan to address issues or progression identified in the data, and to implement changes to the care plan. Further, while these are potentially valuable ways to personalize treatment, access to large amounts of data can expose clinicians to medicolegal risk if data identify concerns that are not acted upon immediately by clinicians. These technologies, therefore, generate an imperative for additional technology infrastructure along with personnel that can recognize, communicate, and mitigate any risks between clinician and patient. Currently, devices may contain a disclaimer that the results of screening tools and other monitoring technologies are not communicated back to the clinician and that the patient should not expect responses to their inputs.

Do interested parties believe digital CBT could be billed using the existing remote therapeutic monitoring codes described by CPT codes 98975, 98980, and 98981? What impediments may exist to using these codes for digital CBT?

APA reiterates that, while monitoring is a key part of digital CBT, codes 98977, 98980, and 98981 only cover clinician time for the implementation of *monitoring* strategies, while the 989X6 PE code covers the cost of the *monitoring* device or technology. RTM codes do not describe the work of

CBT, either digital or analog. CBT in conjunction with other clinical interventions, including the treatment of comorbid conditions, is higher-level, E/M work. The work of the physician is to support the patient in incorporating digital CBT into their plan of care. New digital CBT-specific codes are not required because digital mechanisms are a modality for delivering CBT rather than a distinct service.

What scientific and clinical evidence of effectiveness should CMS consider when determining whether digital therapeutics for behavioral health are reasonable and necessary?

Medical technologies should be held to the same high standards of clinical effectiveness as pharmaceuticals prior to approval and coverage. This would include the delivery of randomized controlled trials in statistically significant percentages of the population with similar clinical characteristics and health-related social needs to those of the Medicare population. This also requires digital control conditions in studies, which are currently rarely implemented. Given the potential of these tools to increase access to care, and to ensure that digital mental health options do not entrench or worsen existing health inequity, there need to be additional studies of real-world engagement and utilization in diverse populations.

If CMS determines the services fit within an existing Medicare benefit category or if other coverage requirements are met, what aspects of delivering digital cognitive based therapy services should be considered when determining potential Medicare payment? Under current practice models, are these products used as incident-to supplies or are they used independent of a patient visit with a practitioner? If used independently of a clinic visit, does a practitioner issue an order for the services?

Digital therapeutics should be used in conjunction with a clinician who may assess the appropriateness of and recommend an app based on the patient's specific diagnosis, clinical and social considerations, and preferences. In most cases, psychiatrists would discuss the recommendation and help the patient engage with the app under an E/M encounter.

Are there barriers to digital CBT reaching underserved populations, and would a supervision requirement impact access to digital CBT for underserved populations?

There are multiple barriers to accessing digital therapeutics that we have covered in previous questions, but a supervision requirement is not one. Supervision requirements help ensure that patients are receiving the most appropriate care possible, rather than patients with reduced access to care being shunted into lower-quality digital services as a replacement for psychiatric diagnostic evaluations, managing psychiatric emergencies, and managing psychiatric conditions with medications.

What strategies, if any, within the digital therapeutics for behavioral health support disadvantaged/hard to reach populations in advancing equity in health care services?

Strategies to increase access include familiar accessibility features, including text-to-speech or increased text size; availability for free or very cheap; ability to use offline in case of limited Wi-Fi or data; ability to email or export data or to send data to a medical record; and options in multiple

languages.[29] Roles like digital navigators can support digital access, literacy, and engagement for these communities and help move from the digital divide to digital inclusion.

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

Opioid Treatment Programs (OTPs)

CMS proposes to allow periodic assessments to be furnished audio-only when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished, and all other applicable requirements are met. In previous final rules, CMS has finalized policies to allow OTPs to furnish substance use counseling and individual and group therapy via two-way interactive audio-video communication technology and audio only telephone calls when audio and video communication technology is not available to the beneficiary. In the CY 2023 PFS final rule (87 FR 69775 through 69777), CMS further extended telecommunication flexibilities for the initiation of treatment with buprenorphine outside of the COVID-19 PHE. Specifically, allowing the OTP intake add-on code to be furnished via two-way, audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. CMS also permitted the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary, provided all other applicable requirements are met.

In this proposed rule, CMS reports that evidence has shown 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. (pg 507) Other evidence also suggests that while Tribal populations, including American Indian and Alaska Natives, have the highest rates of OUD prevalence among Medicare beneficiaries, one-third of these populations do not have adequate access to high-speed broadband and continue to rely on audio-only visits. **APA encourages CMS to make permanent the allowance of periodic assessments to be furnished audio-only when video is not available in order to prevent the unintended consequence of treatment drop-out or inequitable access to lifesaving treatment options.**

[29] M-Health Index & Navigation Database.

Updates to the Quality Payment Program (Section IV)

MIPS Performance Threshold

CMS is proposing to increase the performance threshold to 82 points in 2024, from 75 points in 2023. The agency proposes to use a prior period, or lookback, of three years to establish the performance threshold in 2024 and future years and would use the average of 2017, 2018, and 2019 mean performance data to set the 2024 MIPS performance threshold.

APA strongly agrees with AMA and other specialty societies and urges CMS not to raise the performance threshold to a degree that will penalize more than one-half of MIPS eligible clinicians (CMS predicts 54% will incur a penalty of at least 2.4% with an 82% threshold), who are currently facing near-record levels of inflation coupled with a proposed 3.36 percent reduction to their payment due to Medicare budget neutrality requirements. Compounding this financial distress with an expansion of MIPS penalties threatens the viability of physician practices and patient access to care. At a minimum, to lessen the economic drain on physician practices, CMS should freeze the performance threshold at 75 points.

CMS Proposal to Use a 3-year Prior Period to Establish the MIPS Performance Threshold

Regarding CMS' proposal to use a three-year prior period to establish the MIPS performance threshold, we believe this has promise for improving stability in the program in future years. However, it is appropriate to increase the performance threshold from 75 to 82 points in 2024 based on 2017-2019 data. 2017 data was artificially skewed due to first year program requirements that only required submitting one case for one measure to avoid a payment adjustment. Thus, the majority of submitters who did more than that were top performers and early adopters and not reflective of the majority of MIPS eligible clinicians. 2018, with the 15 pt threshold achievable by only submitting the IA category, was not much better. 2019 is likely the only year that is somewhat valid, but the COVID EUC was applied for 2019, so even that data skews to high performers, or at least early submitters. Cost was frozen from 2019-2021 and many physicians applied for the EUC from cost in 2022, so physicians do not have a real sense of how cost measures will impact them. At 30%, this is too risky. **Therefore, we urge CMS to decrease the performance threshold in 2024 or, at a minimum, maintain the 75-point threshold.**

Quality Category, Data Completeness

https://www.federalregister.gov/d/2023-14624/p-3027

APA does not support CMS' proposal to increase the data completeness threshold starting in 2027. We continue to urge CMS to not move forward with its finalized policy to increase the data completeness threshold to 75 percent starting in 2024 and revisit the policy.

Since 2020, CMS has required physicians to successfully report on a quality measure for 70 percent of all eligible patients (otherwise known as data completeness requirement within the MIPS program). Starting in 2024, CMS will increase the data completeness requirement to 75 percent of all eligible patients and is now proposing to increase the requirement to 80 percent starting with the 2027 performance period. The

challenges will further be exacerbated for participants in the MSSP program since ALL MIPS quality policy now applies to the MSSP quality requirements.

CMS does not seem to understand the difficulty in aggregating data across multiple practice sites. For example, in psychiatry, many clinicians see patients in a hospital-based clinic or provide care in a SNF as well as in their private practice. The hospital or SNF EHR owns the data for patients seen in a hospital-based clinic. If they are not the same vendor, getting hospitals to share data with another EHR or registry has been extremely difficult, nearly impossible to date. Thus, a well-meaning psychiatrist may only be able to submit data for the patients seen in their private practice and hitting even 70% of data completeness is challenging. The EHR vendor may not even realize they are not submitting 100% of patients for the TIN/NPI.

Therefore, we also request that CMS validate its assumption that it is possible to keep increasing the percentage when interoperability and seamless transfer of data is not yet universally available. Therefore, we request that CMS work with a few registries and practices (across specialties and not just in primary care) to compare what patients/data they are able to capture from the practice and/or EHR against what CMS sees for the TIN or NPI in claims.

Proposed implementation of new MVP, including new cost measures, under MIPS

APA does not support the proposed Mental Health and Substance Abuse MVP (MIPS Value Pathway) This includes two new episode-based cost measures (psychosis/related conditions and major depressive disorder) and lacks 3-4 of the of quality measures most commonly reported by psychiatrists from 2019-2021 (data from PsychPRO registry, 2022). It has been documented that psychiatrists are currently more likely to incur a negative adjustment to their payments under MIPS than other physicians.[30] If implemented, their risk increases and the proposals will not only jeopardize the ability of psychiatrists to maintain their practice, but it will disincentivize them from participating in Medicare, exacerbating issues of access for Medicare beneficiaries. **We urge CMS to delay implementation of the MVP and associated cost measures. If a delay is not possible, we urge CMS to include the additional measures explained below (226, 238, 128, and 431).**

The Mental Health and Substance Abuse MVP as currently specified appears to serve only to limit the choices available in a way that provides little benefit to clinicians. Even within traditional MIPS, the selection of measures in the program remains limited across the breadth of the specialty and inadequate to cover the major topic areas of practice for psychiatrists; most mental health clinicians are not able to select a set of measures that are directly relevant to the clinical care they provide. Moreover, the cost and quality measures included in the proposed MVP are not clearly linked, undermining the notion of a conceptually related bundle of measures and activities. **APA recommends the pairing of quality and cost measures that are supportive of each other – i.e., such that greater attention to performance on**

[30] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2790543

quality measures would likely lead to better performance on the cost measure, consistent with the Triple Aim.

Data from the PsychPro registry show that most psychiatrists have been reporting on:

- 130- Documentation of Medications in the Medical Record: we recognize this measure is topped out and not overly relevant;
- 238- Use of High Risk Medications in Older Adults: this measure is also topped out, but is extremely important to psychiatry;
- 128- Body Mass Index (BMI) Screening and Follow-Up Plan: extremely relevant to psychiatry with respect to eating disorders and body dysmorphic disorders; and
- 431- Unhealthy Alcohol Use- Screening and Brief Counseling

None of the above are proposed for inclusion in the MVP.

The other top measures vary between:

- 107-Adult Major Depressive Disorder (MDD): Suicide Risk Assessment: this will be replaced by the new Suicide Safety measures, but it will take time to change documentation practices for clinicians to be able to capture and report on these measures
- 09-MDD: Antidepressant Medication Management
- 134- Preventive Care and Screening: Screening for Depression and Follow-Up Plan
- 383- Adherence to Antipsychotics Medications for Individuals with Schizophrenia

The last 3 measures are included in the MVP, along with the 2 suicide measures.

The next most popular measures were the adult and adolescent tobacco screening measures (226 and 402), which we understand are being collapsed into 226 to include all patients 12 and older.
As this MVP is titled Mental Health *and Substance Abuse*, it seems extremely remiss to leave out the only measures in the MIPS program that screen for tobacco and alcohol abuse, the 2 most commonly abused substances (SAMHSA 2020, in https://www.addictioncenter.com/addiction/10-most-common-addictions/). As the measure set stands, it will add extreme burden for our members to be able to successfully report on 4 of these measures.

The cost measures are the most problematic piece of the proposed MVP. **For the psychosis/related conditions cost measure, APA has expressed concerns throughout the development process about the limitations placed on inpatient psychiatrists to influence care or outcomes outside of the hospital setting.** For example, some patients receive outpatient follow-up visits in other systems, or community settings outside of the original hospital setting. This makes it difficult to hold the inpatient psychiatrist accountable for outcomes once the patient is discharged. Outpatient mental health professionals are in short supply and access to care can be quite challenging. While arrangements for follow-up care can be made while the patient is still in the hospital, there is no guarantee the patient will keep the appointment or change clinicians. There is also substantial geographic variation in the availability of care. Simply

increasing care coordination efforts by inpatient psychiatrists or their treatment team would have little or no effect if there are no community resources available. Furthermore, the fragmented nature of the mental health system means that most readmissions occur at other facilities and the initial psychiatrist will have no feedback on the costs or readmission status of individual patients if this occurs. Most importantly, the quality measures proposed in the MVP with very few exceptions are tracked in the ambulatory care setting. They are not linked to the psychosis/related conditions cost measure and thus, it does not make sense to include this cost measure in the MVP.

APA is similarly concerned that the cost measure for depression does not align with quality care. For most healthcare organizations—particularly those that contract with CMS—depression care is non-revenue generating. The financial argument to providing high-quality depression care is that it reduces total healthcare expenditures. While it is likely true that not all costs related to depression care drive quality equally, we fear that targeting the costs of depression care as a whole will end up paradoxically increasing total healthcare costs for patients who have depression, while also incentivizing poorer-quality care.

Depression costs can be targeted in a way that aligns with quality. Using quality measures to better incentivize the use of measurement-based care in specialty care and primary care through collaborative care programs—which manage mild to moderate depression and anxiety in a low-cost but outcomes-driven way through primary care—would be one strategy that the APA would support. Measurement-based care has been shown to be effective in improving outcomes through repeated measurement. Collaborative care programs have been amply demonstrated to achieve better depression outcomes for patients and reduce total healthcare expenditures. In order to measure this effectively, CMS would also need to support more accurate identification of mild to moderate cases through systematic screening and measurement-based care. We suspect that one of the main reasons Acumen's data seems to suggest that the cost measure is similarly valid across different severity specifications is that the documentation of case severity in current clinical practice is not standardized or accurate.

Proposed Additions, Changes, and Removal of QPP Measures

APA supports the inclusion of the 3 new behavioral health measures proposed for inclusion in the MIPS program and appreciates that they have been proposed across several MVPs.

APA supports the intent of the new measure Connection to Community Service Provider but has concerns about the implementation as it is written. Access to community providers remains extremely variable across the country and it would be challenging to hold clinicians accountable for finding resources in communities that lack the full continuum of care. This measure does not make a distinction between social risk and social needs screening, which are performed very differently, and is not supported by evidence.

APA supports the proposed changes to the 134-Preventive Care and Screening: Screening for Depression and Follow-Up Plan measure, as removing pre-existing depression from the exclusions supports measurement-based care.

APA supports the proposed changes to streamline tobacco screening by bringing the age for screening down to 12 in the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention and eliminating measure 402.

APA does not support the removal of 128- Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan as a stand-alone measure. This is a measure commonly reported by psychiatrists and other specialists that do not perform breast cancer or colon cancer screening or give immunizations. It is relevant to practitioners treating eating disorders as well as obesity, including obesity as a side effect of some antipsychotic and antidepressant medication and may apply to a patient population not yet eligible for breast or colon cancer screening; while those cases would fall out of the denominator, a psychiatrist seeing a patient between the ages of 45 and 75 would be penalized for not performing/referring for breast and colon cancer screening or giving influenza and pneumococcal immunizations under the proposed structure. We recognize that measure 128 has been retained for some MVPs, but it was not proposed for retention in the Mental Health and Substance Abuse MVP. With only the detail specified in the proposed rule, it does not appear that a clinician for whom it is out of scope of practice to screen for certain conditions could report the composite measure for only BMI and/or tobacco screening by reporting only certain numerators. **This would eliminate measure 128 as an eligible measure for psychiatrists, when it has been among the top 6 measures reported by psychiatrists for 5 years.**

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

Sincerely,

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