



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

Submitted electronically

September 27, 2019

Board of Trustees
2019-2020

Bruce J. Schwartz, M.D.
President

Jeffrey Geller, M.D., M.P.H.
President-Elect

Sandra DeJong, M.D., M.Sc.
Secretary

Gregory W. Dalack, M.D.
Treasurer

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-1816

Altha J. Stewart, M.D.
Anita S. Everett, M.D.
Maria A. Oquendo, M.D., Ph.D.
Past Presidents

Eric M. Plakun, M.D.
Vivian B. Pender, M.D.
Kenneth Certa, M.D.
Cheryl D. Wills, M.D.
Jenny L. Boyer, M.D., Ph.D., J.D.
Melinda L. Young, M.D.
Annette M. Matthews, M.D.
Ayana Jordan, M.D., Ph.D.
Rahn Kennedy Bailey, M.D.
Richard F. Summers, M.D.
Rana Elmaghraby, M.D.
Michael Mensah, M.D., M.P.H.
Trustees

Re: [CMS-1715-P] Medicare Program; CY 202 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professional; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations.

Dear Administrator Verma:

The American Psychiatric Association (APA), the national medical specialty society representing over 37,800 psychiatric physicians and their patients, would like to take this opportunity to comment on the 2020 proposed rule on the Medicare Physician Fee Schedule and Quality Payment Program. Our comments focus specifically on issues that affect the care of patients with mental health and substance use disorders (MH/SUDs).

Telehealth Services

APA supports CMS's interest in expanding access to telehealth services. Most psychiatric treatments can be delivered through telepsychiatry, which provides an already vulnerable mental health population with improved access to care in a variety of settings. Case studies and empirical data have revealed that telepsychiatry has no known absolute exclusion criteria, nor contraindications for any specific psychiatric diagnoses, treatments, or populations, including those with substance use disorders.

Assembly 2019-2020

Paul J. O'Leary, M.D.
Speaker

Joseph C. Napoli, M.D.
Speaker-Elect

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

Administration

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

Section 2001(a) of the SUPPORT Act amended section 1834(m) of the Act, adds a new paragraph (7) that removes the geographic limitations for telehealth services furnished on or after July 1, 2019, for individuals diagnosed with a substance use disorder (SUD) for the purpose of treating the SUD or a cooccurring mental health disorder. Section 1834(m)(7) of the Act also allows telehealth services for treatment of a diagnosed SUD or co-occurring mental health disorder to be furnished to individuals at any telehealth originating site (other than a renal dialysis facility), including in a patient's home. There is currently a numeric and geographical maldistribution of psychiatrists in the United States. This is true for both urban and rural areas alike. **We urge CMS to take the steps necessary to eliminate the geographic and originating site requirements for telepsychiatry reimbursement for all patients with**

mental illnesses, not just those diagnosed with a substance use disorder. This would serve to increase access to care for this patient population in urban areas. For instance, many patients diagnosed with a psychiatric disorder may live in an urban area, but within a “transportation desert,” or may be required to spend hours riding public transportation for a single appointment. Additionally, eliminating the geographic/originating site requirements would increase access to care for patients with physical disabilities and for patients whose psychiatric diagnosis precludes them from seeking care. Finally, expanding coverage regardless of the patient’s physical location would also address the stigma associated with seeking care for mental illnesses in the first place, which often results in patients a) not seeking care or b) not maintaining regular appointments with their psychiatrist. Research has shown that improving access to telepsychiatry services results in improved medication adherence, fewer visits to the emergency department, fewer inpatient hospital admissions, and decreased readmissions, all of which serve to increase patient outcomes and lower costs.

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs, and Bundled Payments Under the PFS for Substance Use Disorders

As an organization that represents front-line physicians who treat patients with substance use disorders, including opioids, APA commends CMS for expanding coverage for services provided to patients with opioid use disorders. For the purposes of this letter we will restrict our comments to the proposals put forward regarding coverage of services provided to patients with an opioid use disorder (OUD). **We do, however, strongly recommend that CMS take steps to address gaps in care for all substance use disorders, including dependence on tobacco, marijuana, and alcohol. APA urges CMS to continue to advance solutions that will improve access to effective evidence-based treatment, reduce the stigma associated with substance use disorders, and protect safety net programs that offer valuable coverage for individuals and families in need of treatment.**

The following comments can be generalized across both proposals:

- As with other medical conditions, treatment for opioid use disorder should be individualized and comprehensive, based on patient need and severity of illness. The range and intensity/complexity of services varies over the course of the episode. Intensity/complexity does not always correlate to additional time.
- A comprehensive assessment (and re-assessment as needed) as indicated for co-occurring mental health disorders or other physical health conditions is important in establishing and refining a treatment plan and ongoing management of conditions.
- Patients may benefit from different levels of care at different points in their recovery. For example, outpatient counseling, intensive outpatient treatment, or inpatient treatment; for some this is a chronic illness that will require varying levels of care throughout the course of their life.
- Studies have demonstrated the effectiveness of medication for OUD, especially when combined with counseling and other psychosocial therapies.^{i,ii,iii} Thus, medication for OUD should be prescribed as part of a comprehensive treatment plan that includes counseling and participation in social supports.

APA also encourages CMS to take steps to minimize barriers to medication treatment by easing prior authorization requirements and making available (via coverage and reimbursement) all FDA-approved medications for treating substance use disorders, including long-acting buprenorphine formulations that reduce the risk of relapse and improve adherence. As mentioned previously, the APA supports CMS’s efforts to ensure that any proposed benefit plan that would implicitly or explicitly discourage enrollment by beneficiaries in need of these therapies will not be approved. It is imperative to ensure that Medicare beneficiaries have appropriate

access to medication, and we continue to expect Part D sponsors to include necessary products in preferred formulary tiers, and to avoid placing generic drugs indicated for medication in brand tiers. As CMS has noted via guidance documents, the agency will closely scrutinize formulary and benefit submissions with respect to formulary inclusion, utilization management criteria, and cost-sharing for Part D drugs indicated for treatment.

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Outpatient Treatment Programs

APA fully supports CMS's proposal to create a new coverage category for services provided in the Outpatient Treatment Setting (OTP). We agree with CMS that the existing SAMHSA certification and accreditation process is sufficient and that no additional conditions for participation are required. We also back CMS's proposal to not impose a limit on the number of weeks patients can remain in treatment; treatment should be guided by patient progress and not by an arbitrary limit. We also concur with CMS's proposal to set copayments at zero, which further reduces the barriers to accessing care. We ask that CMS consider extending that policy to services billed in the OTP that are separate from the bundle.

Given the potential range of services and variation in levels of intensity/complexity, particularly at the induction phase, we suggest a careful analysis of existing data be done to ensure that the service components are appropriate and rates adequate to cover the full cost of care. As CMS points out, private payers, Medicaid, and Tricare have already been paying for some or all of these services. A review of those rates and the range of services covered would be critical to establishing appropriate payment. Further clarification is needed with regard to specific services that can be billed outside of the bundle. For instance, it may be more appropriate to bill using existing evaluation and management codes for specific services, such as the initial evaluation, based on the level of complexity or time spent during the patient encounter.

Bundled Payments Under the PFS for Substance Use Disorders

The APA commends CMS for the proposal that attempts to address gaps in coverage for patients suffering from opioid use disorders while reducing administrative burdens for practices providing medication.

As stated in the rule, the bundle includes overall management of care, care coordination, individual and group psychotherapy, and counseling for office-based OUD treatment. CMS indicates this is based on the belief that monthly-reported codes align better with other care management services such as the behavioral health integration services and sees this as being administratively less burdensome for physicians providing care. As proposed, medications and lab testing would continue to be billed separately.

In reviewing the proposal, our members had a number of questions as to how the bundle would be operationalized. We would appreciate further clarification on the following:

- Given the provision of medication is a medical service, it is unclear from the proposal how medical services should be billed. It appears these services can be billed through the use of traditional evaluation and management services in addition to the billing of the bundle if all other criteria are met. We would appreciate further clarification as to how to account for these services if the remaining services (counseling or therapy) are billed within the proposed bundle.
- Members noted that medication for OUD is provided in a variety of settings by both primary care and specialty care providers. Not all practices include the range of professionals licensed to provide the services as currently proposed and not all services or possible providers are currently paid under the Part B program. Further clarification is needed as to the setting in which these bundled services are

most likely to be provided/billed (were these intended for use in intensive outpatient settings or for outpatient practices that provide medication services?). Payment amounts should recognize different types of practice arrangements. CMS should also consider how the bundle would be applied to patients transitioning between levels of care.

- The bundle is based on the Psychiatric Collaborative Care Management (CoCM) codes and includes care management activities as part of the bundled service. It is unclear if other elements of the CoCM services are included, specifically consultations similar to that described in the CoCM codes. Access to relevant consultants would likely be beneficial in increasing the number of physicians treating patients with opioid use disorders, particularly in small practices or rural areas. Clarification as to whether that is included in this proposal is requested.
- The monthly bundle could prove challenging depending on what is minimally required each month. Patient and provider availability may play a role in what services are provided as will patient compliance to their proposed treatment plan. This is further compounded in those instances where care is initiated in the second half of the month. As we have seen with the implementation of the CoCM codes, the time requirements are difficult to meet for those patients enrolled in the program later in the month. Physicians should not be penalized due to the timing of the initial month of care. Further clarification is requested as to what is minimally acceptable within a month in order to bill the service.
- As with existing care management codes, this bundle is billed on the basis of time. We urge CMS to develop reasonable documentation guidelines that reduce the administrative burden associated with time-based billing while ensuring that there is adequate documentation to support the service provided. There also needs to be a mechanism to ensure that appropriate treatment is being provided based on the clinical needs of the patient in a way that addresses concerns about fraud and abuse.
- We have concerns as to how the add-on code for additional time is structured and would like to better understand the billing rationale that indicates that the GYYY3, (*Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure)*) can only be billed after the first 120 minutes or 50 minutes or 60 minutes respectively after the GYYY1 (*Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling: at least 70 minutes in the first calendar month*) and GYYY2 (*Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling: at least 60 minutes in a subsequent calendar month*) rather than at the 16th minute as is currently done under the CoCM codes. The instruction to bill after the first 120 minutes means that a significant portion of work that is provided is not covered. Existing guidelines for other add-on codes for additional time allow for the billing to begin after reaching the midpoint of the add-on code. We urge CMS to modify this proposal to make it consistent with existing billing guidelines for similar services.

APA wholeheartedly supports increased access to appropriate evidence-based treatments for patients with opioid use disorders. While we applaud CMS's effort to improve care for this patient population, we view the proposal as a first step that would benefit from clarification on the topics noted above. We also encourage CMS to further study how to incentivize physicians to care for this patient population. This includes increasing

the number of physicians trained and willing to treat this patient population, as well as incentivizing those physicians who are already waived to provide care to more individuals. We welcome the opportunity for further collaboration on this important issue.

Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

We concur with our colleagues from the University of Washington’s AIMS Center and encourage CMS to provide separate payment for these services in the FQHC/RHC setting. The existing coding options do not adequately describe the work performed. Appropriate coverage is important in ensuring access to these services in these settings.

Physician Supervision for Physician Assistant (PA) Services

APA recommends that CMS maintain current regulations that require physician assistants to provide services under the “general supervision” of a physician. General supervision means that the services of a PA are provided “under the overall direction of a physician,” but the presence of a physician is not required when the PA is providing care. At present there are no state laws that allow PAs to practice independently. We believe the definition of general supervision is broad enough to encompass regulations in those states that have changed the terminology to collaboration rather than supervision, so there is no need to change existing regulations.

Review and Verification of Medical Record Documentation

We applaud CMS for making a concerted effort to reduce administrative burdens through the “Patients over Paperwork” initiative. The documentation changes proposed will streamline communication, and reduce documentation errors moving forward. **APA supports the proposed changes**, which enable physicians, including teaching physicians, to review and verify (sign and date) information documented in the medical record by other members of the treatment team, including residents and students, without having to re-document the information.

Care Management Services

Principal Care Management (PCM) Service

APA supports CMS’s proposal to establish Principle Care Management (PCM) codes that describe care management services for patients with one serious chronic condition. PCM services will be beneficial to psychiatrists caring for patients diagnosed with one chronic mental illness or substance use disorder.

Payment for Evaluation and Management (E/M) Services

APA commends CMS for their “Patients over Paperwork” initiative, including proactive measures undertaken over the past several years to ease the administrative burdens faced by physicians who provide direct patient care. We applaud CMS for supporting a proposal that makes a meaningful attempt to address the complexities of the current evaluation and management documentation guidelines and coding structure. Psychiatrists are treating an increasing number of complex patients based on advances in population-based care and a diminishing psychiatric workforce. Approximately 47.6 million in people aged 18 or older in the United States lives with mental illness, and of those, 11.4 million individuals suffer from serious mental illness. Suicide rates have been increasing with more than 47,000 people dying by suicide in the United States in 2017.^{iv} This is a fraction of those individuals who have considered suicide. Access to psychiatric care is critically important for individuals whose healthcare is covered by Medicare either because of age or disability.

We thank CMS for recognizing the need to review and refine payment policies for outpatient evaluation and management services. **We fully support CMS's proposal to adopt, for 2021, the new coding, prefatory language, and interpretive guidance framework that has been approved by the AMA CPT Editorial Panel** and agree that it will be less burdensome, more intuitive, and will focus care and documentation on what is clinically relevant on the date of service. **We urge CMS to finalize (for 2021), the proposal to adopt the RUC recommended values and times.**

Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm

While we appreciate CMS's concern for patient safety and support CMS's desire to be good stewards of Medicare funds, we do not support CMS's proposal to deny or revoke provider enrollment for any action taken by a state medical board or equivalent entity. This proposal has the potential to further stigmatize individuals suffering from mental health and/or substance use disorders. We ask CMS to clarify if there is evidence that shows a correlation between disciplinary actions taken by state boards of medicine and fraud and abuse within the Medicare program. This proposal has the potential to further stigmatize individuals suffering from mental health and/or substance use disorders. **We urge CMS not to finalize this proposal.**

CY 2020 Updates to the Quality Payment Program

MIPS Program Details

Transforming MIPS: MIPS Value Pathways (MVP) Request for Information

APA appreciates CMS's interest in simplifying the MIPS process by introducing the new MIPS Value Pathway framework, which is focused on improving value, reducing burden, and informing patient choice. As described, the new framework would connect relevant measures and activities across the four performance categories - quality, cost, improvement activities, and promoting interoperability – in a way that is relevant to the population of patients the physician is treating. It appears this could take the form of specialty-specific or condition-specific groupings that physicians would potentially find more relevant to their daily practice. Like CMS, we hope that the MVPs will successfully streamline and simplify the current Quality Payment Program rules so that that APA eligible clinicians (ECs) will have a more meaningful experience in measuring and improving the quality of care they provide.

Consistent with CMS's vision, APA supports the development of meaningful quality measures and performance improvement based on evidence-based practice. APA, in partnership with NCQA, received a three-year grant from CMS to develop a number of process and outcome measures for the outpatient setting focused on measurement-based care, evidence-based care, and care experience, which, when complete will increase the number of measures available. In addition, the APA supports CMS's efforts to tailor reporting of quality measures to the provider's clinical practice. The MVP framework re-conceptualizes MIPS to allow for provider choice of which MVP they participate, which will streamline the process and likely improve participation. If adopted, participants would have the option of choosing a specific MVP in which to participate. This will provide eligible clinicians with the opportunity to have greater decision making in their participation, while CMS is assured that data collected will be analyzed to demonstrate care variation and compare improvements among appropriate eligible clinician populations. We also think that on the basis of their participation in MIPS or MVP, a simple attestation by the physician should be sufficient to meet the requirements for interoperability. This

would reduce the administrative burden and potential barriers to participation associated with that component. Consideration of additional incentives to encourage greater interoperability beyond the minimal level required for reporting could help move a physician or group of physicians along the continuum.

In addition, should CMS choose to move forward with the implementation of the MVP framework, we recommend that additional analyses be done to develop and further refine cost measures that are appropriate for persons receiving care for mental illness. As stated in our March 29, 2019, letter to CMS, we have serious concerns about the structure and attribution methodology of the draft measure for Psychosis and Other Related Conditions. We also agree with other stakeholders who have reported similar problems with the Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) measures already in place. Each of these measures holds physicians accountable for costs beyond their control. If this framework moves forward we strongly urge CMS to pilot test **the proposed MVP (without penalty to the physician), including the individual cost measures, to better understand the impact these components have on controlling costs and/or improving care; as well as identifying any unintended consequences related to use of the measure. CMS can use the data to analyze the relationship among the three components (quality measures, cost measures, and improvement activities) and determine the impact, if any, these have on improving care.** This data will be critical to understanding if a MVP is feasible and will not cause harm in the behavioral health care arena.

Given that the proposal provides a general framework rather than a detailed plan, and in light of the concerns expressed above, the **APA encourages CMS to consider a longer implementation timeline to allow for testing, data collection, and analysis as well as educational outreach to physicians on their participation options. We ask CMS to include relevant stakeholders including psychiatrists and the APA in the development process (both for the specifics of the overall framework as well as for the development of the individual measure sets) from the beginning to provide both clinical expertise and information on the practical realities of implementing this framework.** Access to and review of specialty-specific data sets will be an important component in the development of relevant MVPs. We encourage CMS to create a mechanism to share data in a meaningful way to assist in the development and maintenance of MVPs. This could begin with a review of existing data sets in an effort to identify and prioritize the clinical areas or patient populations for which the development of an MVP is best suited (i.e., sufficient data regarding individual components, overall impact on quality care or cost).

MIPS Performance Category Measures and Activities

Quality Performance Category

Given the potential development and implementation of an alternative MIPS reporting framework, we strongly support making minimal changes to MIPS in the coming year. In particular, we ask CMS to maintain the current quality performance category weight (45%) and data completeness rates (60%) at the 2019 levels to encourage participation and steady rates of data collection in light of the potential for a new MIPS reporting framework. We support maintaining the low volume threshold and ask that this be applied to the MVP program as well. We ask that CMS be judicious in removing measures currently available for use in the program. Consistency provides physicians with a stable reporting methodology, allows for benchmarking across multiple years and eases the burden (cost and time) of having to adjust to multiple changes on an annual basis. APA members have raised concerns about the insufficient number of measures available that are relevant to their practice. We ask CMS to be both mindful of the impact removing any measure has on the ability of a physician to report and to remove requirements that force physicians to report a quality measure simply for the sake of meeting a reporting requirement (i.e., six measures, all in a specialty measure set). Eligible clinicians should be

incentivized to select measures that align with the actual scope of a patient encounter. This promotes use of more meaningful measures as well as identifying measures with greater utility in clinical practice.

Updates to the MIPS Specialty Measure Sets for 2022 Payment

APA supports the inclusion of various behavioral health quality measures within the specialty measures sets. However, we do have some questions based on measures that were included within some, but not other, measure sets.

B.6 Family Medicine and B.7 Internal Medicine Sets both include several quality measures that address mental health and substance use disorders. Given the high rates that patients are assessed or treated for these conditions, we are curious as to why Q# 107: *Adult Major Depressive Disorder (MDD): Suicide Risk Assessment* and Q# 391: *Follow-Up After Hospitalization for Mental Illness (FUH)* were excluded from both measure sets. This is concerning considering the other quality measures included in these sets address MDD as other serious mental illnesses. **We recommend the inclusion of these quality measures (Q# 107 and Q# 391) within both sets since the omission of these measures presents a threat to patient safety.**

B.8 Emergency Medicine Set includes Q#107: *Adult Major Depressive Disorder (MDD): Suicide Risk Assessment*, however, it does not include any other quality measures for mental or substance use disorders. **Given the rise in adolescent suicides, we recommend the inclusion of Q# 382: *Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment*. We further request clarification on why other mental and substance use disorder measures were omitted from this set.**

B.14 Pediatric Medicine and B.19 Mental/Behavioral Health Sets both **include** Q# 366: *ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication*. APA continues to remain concerned by this measure's use in the HEDIS measure set, as well as in the MIPS quality performance category since it was first adopted into the program.

The measure's specifications for medication follow-up visits are not consistent with standards issued by the Drug Enforcement Administration (DEA). The statement addressing Schedule II controlled substances is included in the DEA publication, "Practitioner's Manual an Informational Outline of the Controlled Substances Act 2006." This document, developed to assist physicians "and other registrants authorized to prescribe, dispense, and administer controlled substances in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the practitioner's profession." According to the Practitioner's Manual, issuing multiple prescriptions for Schedule II controlled substances, such as stimulants, cannot exceed more than a total 90-day supply of Schedule II drugs, and each prescription is limited to 30 days." In contrast, this Core Set measure includes a minimum requirement of two additional follow-up visits (which could include one being a telephone contact) within the first nine months of prescribed stimulant medication. APA's Council on Quality Care, comprised of national leaders in quality measurement, raised serious concerns about the frequency of medication safety monitoring visits for children prescribed Schedule II drugs. Details are summarized in a Letter to the Editor in the *Journal of the American Academy of Child and Adolescent Psychiatry*, which was signed by six members of APA's Councils on Quality Care and Children, Adolescents, and their Families.

In addition, the Continuation Phase is restricted to a small proportion of children who have relatively long term, continuous adjudicated pharmacy claims for stimulant medication. Interpretation of these data is problematic because a large proportion of children are not included in the denominator for the Continuation Phase. In short, the relatively high rate of stimulant treatment non-adherence, a potential target for quality improvement

especially among low-income children, is not transparently reported. Further, while APA supports CMS's implementation of quality measures endorsed by NQF, this measure was endorsed for meeting NQF's scientific acceptability criteria using data at the health plan level but not at the individual or provider level, which would be more applicable for use by CMS. Among states reporting adherence to this measure, rates vary widely and approaches to measure and publicly reported adherence rates are not standardized.^{vi}

Together, these concerns support our recommendation that this measure be removed until revised to improve the frequency of in-person (or by telehealth) medication follow-up visits, clearly specify rates of stimulant medication non-adherence, develop a more standardized approach for measuring and reporting adherence, and to test data that establishes the relationship between measure adherence and meaningful clinical outcomes.

B.19 Mental/Behavioral Health Set (continued)

APA strongly supports inclusion of measures related to the identification and treatment of depression as part of the quality measures program. Depression remains a major public health issue that directly or indirectly affects a significant fraction of the population annually and during their lifetimes. It is associated with substantial days lost to disability and increased rates of suicide as well as in increased costs and the worsening of outcomes related to other health conditions. Despite these major impacts on health, depression continues to be under-recognized and under-treated.

APA is concerned by the proposed removal of the Q#325: *Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions*. With APA's role as steward of this measure, clinical experts responsible for the oversight of quality measures at APA maintain this measure's importance in assuring the delivery of high-quality care for those with MDD and medical comorbidities.

We appreciate the stakeholder comments shared as part of the rationale for the measure's proposed removal. We understand the concerns regarding the burden imposed on "clinicians to retrieve specialists' reports for all patient visits." Since this measure is to be reported no more than one time during the performance year, APA will work with its measure development team and clinical experts to determine whether this is a minimal change to the measure's technical specifications, or if this will require a more substantive update.

We disagree with the assertion that this measure is duplicative to Q# 374: *Closing the Referral Loop: Receipt of Specialist Report*. To meet Q# 374's numerator, a referral must occur. Without a referral, a report is not sent, no matter the reason for the encounter. Further, Q# 374 is strictly applicable to the initial encounter. The specifications do not include communication between the clinicians at future follow-ups. In contrast, Q# 325 is intended to capture communication regarding patients treated for MDD and a comorbid condition over time. Considering the comments detailed above, APA plans to review the specifications for Q# 325 to determine a plan that will reduce the burden imposed by the measure. However, given the differences between these measures, and the need to ensure that those with serious mental illness, like MDD with comorbid medical conditions, maintain care from both clinicians, we strongly recommend that this quality measure remain in the Mental/Behavioral specialty measure set.

APA strongly suggests that measures Q# 371: *Depression Utilization of the PHQ-9 Tool* and Q#411: *Depression remission at Six Months* be retained in addition to Q# 370: *Depression Remission at Twelve Months*. Although Q#370 would seem to encompass measures Q#371 and Q#411 and make them superfluous, there are significant advantages to retaining all of these measures.

Given the current fragmentation of the health care delivery system and the infrequency with which most individuals are seen by their physicians, it is essential to incentivize use of measures such as the PHQ-9 on a

regular basis. Measure Q#371 Depression: Utilization of the PHQ-9 Tool accomplishes this goal. In addition to helping clinicians identify depression when it is present, administration of the PHQ-9 helps clinicians determine the severity of the patient's depression and can help guide decision-making, even if the patient's depression is not in remission. The PHQ-9 also includes a question related to suicidal ideas, which is an important element of assessment, independent of whether an individual meets other criteria for depression, particularly with the continued increase in suicide rates nationally. Retaining measure Q#371 will give clinicians appropriate credit for making the PHQ-9 a routine and integral part of their workflow and will foster enhanced screening for depression and suicidal ideas as well as ongoing assessments of depression severity to guide measurement-based care.

APA also recommends retaining measure Q# 411: Depression Remission at Six Months, which assesses remission of depression at 6 months. The rationale for removing this measure quotes the APA's practice guideline on treatment of patients with MDD in noting that relapse is common in the initial 6 months after depression remission and in providing a definition of continuation therapy. While these quotations are accurate, they do not support a rationale for removal of this measure. The measure of depression at 12 months (measure Q#370) includes individuals who are seen and have a PHQ-9 completed within 30 days (+/-) of the 12-month time point. This may not capture all patients who have been treated for depression (e.g., patients seen by a psychiatrist who have remitted and then returned to their primary care physician for ongoing care). Clinicians who do not typically follow patients themselves for a full 12-month period may choose not to report this measure rather than be penalized for a measure that incorporates an arbitrary 12-month time point. Having a 6-month measure available in addition to a 12-month measure also has the advantage of incentivizing more rapid detection of a clinical change in symptoms of major depression, building additional capacity to adjust evidence-based treatments to treat or continue to support remission. This enhanced capacity to provide measurement-based care is significant because major depression is a chronic, debilitating disorder with substantial risks (e.g., suicide, substance abuse) and societal costs (i.e. academic underachievement, unemployment).

APA continues to support, in alliance with our medical and social work colleagues, quality measures to monitor adherence to antipsychotic medication for persons with serious mental illness. (Q#383 Adherence to Antipsychotic Medications for Individuals with Schizophrenia found in the core measure sets for Family Medicine, Internal Medicine, Mental Health, and the set proposed for Social Work). However, improving antipsychotic medication adherence without also improving medication safety monitoring is insufficient and may increase risk of undetected metabolic syndromes in children and adults. Thus, we strongly advocate for use of the NQF-endorsed measures related to monitoring risk of diabetes and cardiovascular disease (NQF Q#1932, 1933, 1934), with priority placed on Q#1932, which proactively screens for diabetes among persons with schizophrenia or bipolar disorder on antipsychotic medication.

B.18 Neurology Set includes several measures that MIPS participating psychiatrists implement within their practice. Further, APA is co-measure owner of the following measures within this specialty measure set, which includes the following measures:

- Q# 283: *Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management*,
- Q# 286: *Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia*,
- Q# 282: *Dementia: Functional Status Assessment*, and
- Q# 288: *Dementia: Education and Support of Caregivers for Patients with Dementia*.

Unfortunately, **APA is not referenced as a measure steward alongside the American Academy of Neurology. We request this edit is updated with the final rule.**

APA does not support the removal of Q# 131: *Pain Assessment and Follow-up*. The statement that this measure may have the unintended consequence of encouraging excessive prescribing greatly fails to acknowledge the complex situation that led to the opioid crisis in the US. The APA believes this measure should be maintained given the large population (approximately 100 million) of Americans who live with chronic pain. The measure focuses on appropriate follow-up, which is not limited to medication use. Additionally, the expansion of the measure to include patients with severe incapacities, including dementia, is needed for psychiatry. A separate measure maintained by the American Academy of Neurology (AAN) and APA specifically addressing pain for patients with dementia could be retired given this measure's proposed expansion to include those who are non-verbal.

APA does not support the removal of Q# 282: *Dementia Functional Status Assessment*. The proposed duplicative measure Q# 182: *Functional Outcome Assessment* focuses on the use of physical therapy tools and as such is not applicable to this patient population. It is APA's opinion that the barriers to available tools prevent the measure from being broadly used by psychiatrists. The AAN and APA remain committed to measure harmonization and expanded the denominator to include physical therapy and occupational therapy as a result.

APA does not support the removal of Q# 288: *Dementia Education and Support of Caregivers for Patients with Dementia*. CMS has indicated an overlap with the safety concern screening and follow-up for patients with dementia measure. However, the measure numerators are substantially different warranting use of both measures in MIPS. The safety measure is intended to ensure appropriate follow-up is taken to remove and address patient concerns that may lead to unintended injury of patients and caregivers. The education measure is intended to address the risk caregivers face regarding their own mental health as a result of caring for patients.

Cost Performance Category

We encourage CMS to maintain the current cost measure category weight (15%) at the 2019 levels. This will provide an opportunity for CMS to address the concerns raised by multiple stakeholders regarding methodology while not further penalizing physicians, including psychiatrists, as they try to understand and respond to the feedback they have received. Time is needed to identify ways to further refine the attribution methodology to ensure that physicians are not held accountable for costs of care that are beyond their control. We urge CMS to use the data currently available on the existing cost measures to better understand if the measures are accounting for costs appropriately and, further, to understand how costs may or may not impact quality before adopting additional measures. The MVP framework, if adopted, could offer an opportunity for a more targeted approach.

Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) Measures

We agree with the American Medical Association in asking that the TPCC and MSPB measures be removed from the MIPS program until concerns about the underlying methodology and validity of the measures are addressed. The MVP framework could provide an opportunity to pilot test new cost measures on a smaller scale and in such a way that they are validated and actionable.

Request for Comments on Future Potential Episode-Based Measure for Mental Health

As previously stated in our March 29, 2019, letter to CMS, we have serious concerns about the draft episode-based cost measure for psychosis and other related conditions. As currently constructed, the measure could have a significant negative impact on the provision of mental health services to the most vulnerable segment of our patient population. This measure, as likely others, raises important questions related to the appropriate

follow-up window for an episode of care and adjustment for clinical complexities and social determinants of health that perpetuate disparities.

It appears that the approach used for the development of this measure is the same used in the development of the other episode-based cost measures that target medical conditions such as follow-up after discharge from a common orthopedic surgical procedure. In these case scenarios it is likely that the physician rounding in the inpatient setting will also see the same patient in his/her outpatient office (or group practice). To hold inpatient psychiatrists responsible for access to and timely follow-up outpatient care for persons with psychotic disorders is not appropriate. While inpatient psychiatrists do their best to treat patients in a way that will prevent rehospitalization, there is no recognition in the proposed measure that the inpatient psychiatrist rarely serves as the provider for follow-up outpatient care. As a result, and similar to the concerns noted regarding the TPCC and MSPB measures, individual psychiatrists are being held accountable for costs beyond their control.

Successful transitions from inpatient care to the community often demand navigating a complex, fragmented health care system. In its December 2017 report, *The Way Forward: Federal Action for a System That Works for All People Living with SMI and SED and Their Families*, the Interdepartmental Serious Mental Illness Coordinating Committee included recommendations for providing “a comprehensive continuum of care for people with SMI and SED.” National recommendations for a comprehensive continuum of care have yet to be established. In addition, the challenges to transition from inpatient to outpatient care are often accentuated for persons suffering chronic psychotic disorders. Influential patient-level factors include lack of primary supports, absence of an ongoing relationship with an outpatient provider prior to admission, clinical comorbidities (i.e., co-occurring substance use disorders, atherosclerotic cardiovascular disease), and disproportionately high negative social determinants of health (i.e., poverty, unemployment, housing and food insecurity, stigma). At the system level, this vulnerable population faces greater barriers that have a well-established negative impact on the cost and availability of care ---inadequate insurance coverage, a fragmented system of care, and lack of access to specialty care. This includes a lack of an intermediate level of care, due in part to lack of coverage, that is similar to rehabilitation settings (step-down care) that exists for patients discharged for medical conditions. This transition is further complicated by the maldistribution of outpatient mental health services, which often hinders the patient’s ability to receive timely follow-up treatment.

Also, traditional case management services often do not adequately meet the needs of individuals with severe mental illnesses who are transitioning from inpatient to outpatient care. Additional work, including consideration as to how accountability for this interaction can best be attributed and measured needs to be done to build on what we know now and identify best practices that can be effectively implemented. More research needs to be done to identify the components necessary to increase successful transitions and begin to make a meaningful impact on the cost of care. ^{vii, viii, ix}

As currently constructed, this measure would be more appropriate for the measure to be applied to a health system or managed care organization and not to an individual physician. This may be why members of the technical expert panel convened to review the measure were supportive; many were from large systems that are more readily able to impact care across settings in a meaningful way.

Regarding the reference to parity, the Mental Health Parity and Addiction Equity Act (MHPAEA) does not apply to Medicare. Even if it did, there is nothing that requires that something must be done for mental health/substance use because it has been done for medical/surgical. In fact, it is the reverse - you cannot do something restrictive for mental health/substance use that you do not restrict for medical/surgical. Parity offers absolutely no policy basis, rationale, or support as proposed here.

While the development process put in place by CMS and Acumen, LLP, to define the measure set has been collaborative, the lack of relevant key stakeholders (i.e., social workers, psychiatric nurses, care managers) to represent the individuals who play a significant role in the transition process may have contributed to the measure's failure to account for the complexities of post-hospitalization follow-up. There is also a lack of evidence supporting the scientific acceptability for the measure in the field testing. No preliminary findings using existing publicly available data sources to support the reliability or validity of this measure are reported, a requirement when applying for NQF endorsement.

We support CMS's vision to implement measures for which adherence drives improvement in care, however large-scale use of this measure is premature and as currently specified the episode of care costs for psychosis cannot be attributed to the provider or even hospital. **We urge CMS not to implement this measure given the inappropriate attribution methodology, inadequate stakeholder input, insufficient evidence of scientific acceptability, and the lack of support from NQF.** We welcome the opportunity to partner in future research or demonstration projects that would allow for the identification of more appropriate cost measures related to mental health. To start, the MVP framework may provide an opportunity to pilot test new cost measures on a smaller scale and in such a way that they are validated and actionable. We look forward to working collaboratively with CMS to improve the quality of mental health care for persons across the lifespan.

Promoting Interoperability

The APA acknowledges the success of the HITECH Act and the original Meaningful Use program in incentivizing the adoption of electronic health record (EHR) systems into practice, especially among hospitals. The APA also appreciates CMS's commitment to reducing administrative burdens associated with EHR adoption and utilization with respect to the MIPS program and supports CMS's commitment to do so for inpatient and critical access hospitals through this IPPS proposed rule.

As the APA has detailed extensively in previous letters, the focus on true interoperability—rather than on arbitrary, measure reporting thresholds with respect to EHR use—should remain the cornerstone of the Medicare EHR Incentive Program. As such, the APA appreciates the current proposed rule's emphasis on using EHRs to promote interoperability, as well as the overall reduction of mandatory reporting thresholds.

First, the APA supports the performance-based approach to determining eligible professionals' scores on Promoting Interoperability. While questions remain about the direct correspondence of these activities with improved patient outcomes, the revised scoring methodology for reporting year 2020 (RY 2020) will allow psychiatrists to pick-and-choose among measures that best meet their strengths with a focus on health-data exchange, patients' access to their records, and open Application Programming Interfaces (APIs) to facilitate the movement of patient data across systems. Many CEHRT systems used by psychiatrists do not directly mirror psychiatric care workflows, so offering psychiatrists some the ability to select those measures most germane to them is appreciated.

Similarly, the APA also appreciates the efforts of CMS over the past several reporting years to reduce administrative burdens within the EHR Incentive Program that have been time-consuming or otherwise not truly aligned with the meaningful use of EHR systems in general. **The APA appreciates that the scoring methodology in this proposed rule takes into consideration that eligible professionals are not always able to have their patients engage with the EHR, thereby allowing for the scoring of the different objectives and embedded measures to be weighted accordingly.**

Finally, some psychiatrists may find the remaining measures (e.g., Supporting Electronic Referral Loops by Sending Health Information; Provide Patients Electronic Access to their Health Information) challenging due to the unique nature of psychiatric workflows. **The APA appreciates the proposed rule's elimination of many of the arbitrary thresholds and administrative burdens associated with these types of reporting activities required under the current reporting program. The APA also supports removal of the "Verify Opioid Treatment Agreement" measure, as we suggested in our previous letter for RY2019. We also support keeping the Query of Prescription Drug Monitoring Program (PDMP) as a bonus, rather than requiring it as a part of the Promoting Interoperability performance category score.** As detailed in the Rule, it would be premature to require this measure since there is currently poor integration between PDMPs and EHRs. Hopefully, as various components of the 21st Century Cures Interoperability and Information Blocking proposed rule are implemented, software vendors—using a common standard, like the Fast Healthcare Interoperability Resources (FHIR)—will begin to address this issue.

Request for Information (RFI) on a Metric to Improve Efficiency of Providers within EHRs

The following comments are in response to the multiple bullet points posed within the RFI. The APA strongly recommends that the ONC incorporate these suggestions into its forthcoming EHR Reporting Program, for which APA submitted comments in 2018.

Documentation in the EHR: EHRs possess features that have the potential to make the practice of medicine easier (e.g., electronic prescribing, electronically sending patients messages and educational materials, ubiquitous legibility of documentation, the inherent capacity to view documentation offsite) and help physicians to measure the patient encounter at the point of care. Unfortunately, physicians are spending more time documenting the encounter in the EHR relative to the amount of time spent face-to-face with patients.

Some of this burden could be mitigated by the reduction of complicated—and often redundant—documentation requirements related to quality reporting programs (e.g., various requirements of both the Joint Commission and CMS conditions of participation), documentation specific for the Medicare program for different clinical roles within a practice, E/M coding requirements and inpatient multidisciplinary treatment plan requirements, the latter two of which are not well supported for psychiatry in most EHRs. **As a part of the certification process, the ONC should require vendors to work with clinician-expert partners to identify areas where the same level of data could be streamlined and/or easily imputed based on a minimal number documented entries/steps would be helpful in ameliorating the burden associated with these various reporting programs.**

Seamless Integration of Prescription Drug Monitoring Databases with EHRs: **As a cross-cutting issue between vendors and clinicians, the certification process should collect information on how well EHRs integrate with Prescription Drug Monitoring Program (PDMP) databases and how much time it takes for clinicians to complete this documentation in the patient record.** By collecting this information and making it transparent, the APA hopes that it might incentivize vendors to begin using a common standard and/or legislators to mandate a solution.

The APA acknowledges that integration of these two systems is a challenge due to the various legal hurdles between individual states sharing information as well as the lack of data standardization within the collaborative data network between state PDMPs. However, clinicians are currently burdened by having to leave the screens of the EHR, log into the state PDMP web site, search for each patient's name, and then return to the EHR to complete their task. This is time-consuming and results in fragmented patient data.

The ONC should establish benchmarking for common clinical tasks in EHRs and these benchmarks should be reported through the forthcoming EHR Reporting Program. When selecting an EHR, it would be helpful to have

baseline data on how systems compare to each other with respect to the *time* and *subjective ease* it takes to complete common tasks, such as finding a patient, completing a chart review, messaging a patient, electronic prescribing, creating and documenting a progress note, and so on. **The APA recommends that the ONC contract with a third party to perform such benchmarking using sample workflows tested with sample participants.** Such benchmarking could be completed for a discrete set of clinical tasks within EHRs for specialties and would provide helpful information to specialty providers when selecting an EHR. Examples of such benchmarks include the time and subjective ease required for “breaking the glass” for access to sensitive information, retrieving external health systems’ charts (e.g., requesting, downloading, and viewing notes from other regional health systems), finding and contacting the primary care provider, tracking medication history longitudinally (including long-acting injectable or implanted medications).

Include information from providers and vendors on the privacy/security features of EHRs. While the APA generally advocates for providers to have access to all records (especially when it comes to patient substance use disorder information), there are scenarios where it would be useful to granularly mark/tag specific patient information as confidential, when appropriate. These are not unique to psychiatry, and apply, for example, to the care of adolescents, to reproductive health issues, and to the care of individuals who are known to health system employees (e.g., current relatives, ex-spouses, neighbors, locally prominent people, public figures, etc.). **The APA recommends that vendors and providers report on their EHR's capacity to perform such granularization of data.** For products that are not capable of performing these functions satisfactorily, these could be built around the Family Health History standard (170.315 (a) (12) 2015 CEHRT) or, the ONC could make required the DS4P sending and receiving standards (170.315 (b) (8); 170.315 (b)(8), 2015 CEHRT), with appropriate incentives to developers to offset downstream costs to consumers, rather than making them optional for vendors, in future iterations of the EHR Certification Program.

The APA welcomes the opportunity to further discuss any of the issues raised in this letter. Please contact Rebecca Yowell, Director of Reimbursement Policy, byowell@psych.org or 202-683-8298.

Sincerely,



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

ⁱ Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63, Executive Summary. HHS Publication No. (SMA) 18-5063EXSUMM. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018.

ⁱⁱ Substance Abuse and Mental Health Services Administration. Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide. HHS Publication No. (SMA) 14-4892R. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.

ⁱⁱⁱ NIDA (2009). Principles of drug addiction treatment: A research-based guide (2QPP pnd ed.).

^{iv} Substance Abuse and Mental Health Services Administration. (2019). Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19-5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>.

^v Zima BT, Norquist G, Altchuler SI, Behrens J, Iles-Shih M, Ng YKW, Schaepper MA. Office visits to monitor stimulant medication safety and efficacy: recommended care. *J Am Acad Child Adolesc Psychiatry*. 2018;57(6):438-439. <https://doi.org/10.1016/j.jaac.2018.02.015>.

^{vi} Zima BT, Edgcomb JB, Shugarman SA. National child mental health quality measures: adherence rates and extent of evidence for clinical validity. *Current Psychiatry Reports: Public Policy and Public Health*. 2019; 21: 6. <https://doi.org/10.1007/s11920-019-0986-3>.

^{vii} Gaynes BN, Brown C, Lux LJ, et al. Management Strategies To Reduce Psychiatric Readmissions [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2015 May. (Technical Briefs, No. 21.).

^{viii} Care Transition Interventions to Reduce Psychiatric Re-Hospitalizations. Alexandria (VA): National Association of State Mental Health Program Directors; 2015 September.

^{ix} Smith TE, Abraham M, Bolotnikova N, et al. *Psychiatric Services* 2017 68:1, 92-95.