AMERICAN PSYCHIATRIC ASSOCIATION

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

March 5, 2018

Demetrios Kouzoukas
Principal Deputy Administrator and Director, Center for Medicare
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Room 305H-02 / Mail Stop 301H
Washington, DC 20201

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter (CMS-2017-0163)

Dear Principal Deputy Administrator Kouzoukas:

The American Psychiatric Association (APA), the national medical specialty society representing over 37,800 psychiatric physicians and their patients, would like to take the opportunity to comment on the 2019 Draft Call Letter for Medicare Advantage (MA) and Part D plans, in the notice referenced above. Our comments focus specifically on issues that impact the care of patients with mental health and substance use disorders (MH/SUDs), particularly (1) access to medication assisted treatment; (2) opioid potentiator drugs; (3) enforcement actions for provider directories to ensure network adequacy; and (4) quality measures.

The APA welcomes the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on these critical issues. It is important for CMS to ensure the receipt of well-rounded expert opinions on the subject matter included in this Draft Call Letter, and we remind the agency that collecting expert opinions takes time. For future draft call letters, we request that the public be offered a comment period greater than 30 days.

I. Access to Medication Assisted Treatment

The APA supports efforts to minimize barriers to medication assisted treatment (MAT) by easing prior authorization requirements and making available all FDA-approved medications for treating substance use disorders, including long-acting buprenorphine formulations that reduce the risk of relapse and improve adherence. The APA also supports the CMS position that benefit designs that would substantially discourage enrollment by beneficiaries who need these therapies will not be approved. We continue to expect Part D sponsors to include products in preferred formulary tiers, and to avoid placing generic drugs indicated for MAT in brand tiers. It is imperative to ensure that Medicare beneficiaries have appropriate access to medication-assisted treatment (MAT). As CMS has previously noted in call letter guidance, 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 MAT.

II. Opioid Potentiator Drugs

The Draft Call Letter requests public comment about the potential overuse of gabapentin and pregabalin with opioids, whether an additional flag would be useful for Part D sponsors, and how the case management approach could help with gabapentin/pregabalin-opioid misuse and with other potentiators. CMS also requests comments regarding other potentiator drugs that might be added to the Overutilization Monitoring Systems (OMS) and the utility of adding such drugs that may increase the risk for overdose when used with opioids.

The APA supports monitoring for misuse and obtaining more information about the risks, prior to including an additional utilization flag that could impede beneficiary access to treatment. There has been a shift in using gabapentin and pregabalin for patients with pain as we are reducing our reliance on hydrocodone and oxycodone. These have been helpful for individuals with co-occurring pain and opioid use disorder.

III. Enforcement Actions for Provider Directories to Ensure Network Adequacy

CMS recognizes that accurate provider directories are important to consumers' ability to make informed decisions as well as their ability to access care. To that end, CMS has mandated that dual Medicare/Medicaid plans submit network information annually to CMS for review. This is to ensure that Medicare/Medicaid plans maintain a network of providers that is sufficient in number, variety, and geographic distribution to meet the needs of enrollees. The APA applauds these efforts and the use of quantitative measures, rather than a "reasonableness" standard, to determine whether a network is indeed sufficient. In addition to the current data reporting points, it is essential that CMS also review other appropriate network performance measures, such as out of network utilization, volume of claims made by providers, and emergency room utilization.

The APA also applauds CMS's plans to monitor provider directories for accuracy and initiate appropriate compliance and/or enforcement actions, and to assess civil penalties for violations. On January 31, 2018, CMS announced results from the second of its three studies of provider directories and found that 52.2 percent of provider directory locations listed in the online directories were inaccurate — an increase from 45.1 percent reported in CMS's first study dated January 13, 2017.[1]

Errors like those identified in the 2017 report, included: (a) the provider not being at the listed location, (b) incorrect phone numbers, and (c) the provider not accepting new patients when the directory indicated that they were. CMS identified several common reasons for directory inaccuracies, including: group practices appearing to provide care at the group level rather than at the provider level; general lack of internal audit and testing of directory accuracy among many Medicare Advantage organizations (MAOs); and instances in which calls to various providers' offices resulted in determinations that the provider had retired or was deceased. In its report, CMS concluded that plans are not adequately maintaining the accuracy of their directories, which is a problem widespread throughout the industry, and that the plans are in the best position to ensure the accuracy of their

[1] Centers for Medicare and Medicaid Services. Online provider directory review report. U.S. Department of Health and Human Services. https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Round_2_Updated_1-31-18.pdf.

plan documents. **The APA agrees, and recommends that CMS put the burden on the plans to prove that their directories are accurate. Plans should be required to submit documentation showing they have performed audits or other testing of the accuracy of their provider directories.**

IV. 2019 CMS Display Measures

We are pleased to learn that quality measures are being considered for development that address APA priority areas. Given the evolution of the national quality landscape and fluctuating gaps in care, we appreciate the opportunity to provide our unique expertise to assist in the improvement of patient care.

Potential Modifications to Existing Star Ratings Measures

Antipsychotic Use in Persons with Dementia: This measure examines the rates of inappropriate antipsychotic prescriptions for patients with dementia. Like other quality measures implemented by CMS, this measure is intended to reduce *inappropriate* prescribing practices for this patient population. As such, the measure exclusions consist of patients with schizophrenia, Tourette's Syndrome, Huntington's Disease, and bipolar disorders, but not schizoaffective disorder. However, the literature regarding the use of antipsychotics to treat schizoaffective disorder indicates both the efficacy and the safety of these medications in older adults. We share the limited list of citations below, supporting the use of antipsychotics in patients with schizoaffective disorder, including older adults.

- Glick *et al.* performed a post-hoc analysis examining the efficacy, safety, and tolerability of aripiprazole in patients with schizoaffective disorder and found significantly greater improvement from baseline to endpoint with aripiprazole, as compared with a placebo, on the Positive and Negative Syndrome Scale (PANSS), both overall and with respective to positive symptoms.[2]

- Zisook *et al.* found in their study of augmenting antipsychotic use with a selective serotonin reuptake inhibitor (SSRI) in patients with suicidal ideation that 41 percent of patients were diagnosed with schizoaffective disorder. Of that subgroup, 10 percent were taking first generation antipsychotics, 71 percent taking second generation antipsychotics, and 19 percent were on both—an indicator of its pervasiveness as a therapy.[3]

- Talaslahti *et al*. found the use of atypical antipsychotics increased while the use of typical antipsychotics (haloperidol, loxapine, thioridazine, molindone, etc.) decreased in older outpatients with schizophrenia from 1998-2003 according to the Finnish Hospital Discharge Register, and this included a subgroup of schizoaffective patients. Among other reasons, one explanation for this change could be due to atypical

[2] Glick ID, Mankoski R, Eudicone JM, Marcus RN, Tran Q-V, Assunção-Talbott S. 2009. "The efficacy, safety, and tolerability of aripiprazole for the treatment of schizoaffective disorder: results from a pooled analysis of a sub-population of subjects from two randomized, double-blind, placebo-controlled, pivotal trials." *Journal of Affect Disorders*. May 2009: 18:26.

[3] Zisook S, Kasckow JW, Lanouette NM, Golshan S, Fellows I, Vahia I, et al. 2010. "Augmentation with citalopram for suicidal ideation in How to move bar above footnots to left border?-aged and older outpatients with schizophrenia and schizoaffective disorder who have subthreshold depressive symptoms: a randomized controlled trial." *Journal of Clinical Psychiatry*. 71(7); 915:22.

antipsychotics lacking the Parkinsonian side-effects of the typical antipsychotics, making them a safer option for pharmacotherapy.[4]

- The Joshi *et al.* study found in a large schizoaffective mixed-age population (2,713 people) that 64.4 percent of patients were on antipsychotics at baseline, and at a later follow-up, 74.8 percent of patients were on antipsychotics, leading the authors to determine that antipsychotics are considered the "cornerstone of treatment" for schizoaffective disorder.[5]

With the evidence supporting the use of antipsychotics for these patients, we recommend that CMS add schizoaffective disorder to the list of diagnostic conditions excluded from this measure. It is necessary for the measure developers to retest the quality measure to determine the rate of improvement when all these conditions are excluded. Retesting this measure is also highly recommended because a diagnosis of schizoaffective disorder is often used when the clinician is uncertain whether a patient has schizophrenia or bipolar disorder. Consequently, the data collected is substantially inaccurate and should not be relied upon to illustrate the degree of quality care administered to Medicare Part D beneficiaries. The data source for this measure is pharmacy claims, which generally provide only the principal diagnosis. Clinical information (in the form of a diagnosis code) that would justify antipsychotic use in patients with dementia is not reflected. Therefore, the justification for appropriately prescribing an antipsychotic outside the exclusion criteria is not easily determined. The unintended consequence is that the rating system incorrectly displays the administration of poor quality care, when in fact the care was appropriate.

The APA strongly recommends that the raw measure data be subject to risk adjustment before consumers and others use the Star Ratings or the data to evaluate the quality of care administered. This is critical to avoid penalizing the wrongful assignment of poor care quality ratings to plans that cover the costs of antipsychotics for patients who need them.

Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer: This is a set of three measures focused on reducing dangerous opioid prescribing practices.

1. Use of Opioids at High Dosage in Persons without Cancer (OHD): This measure focuses on identifying plans that prescribe opioid medications for the treatment of pain management. It captures the proportion of patients receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine milligram equivalents (MME) for 90 consecutive days or longer.

2. Use of Opioids from Multiple Providers in Persons without Cancer: This measure looks at the proportion of patients receiving prescriptions for opioids from four or more prescribers AND four or more pharmacies.

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[4] Talaslahti T, Alanen H-M, Hakko H, Isohanni M, Häkkinen U, Leinonen E. 2013. "Change in antipsychotic usage pattern and risk of relapse in older patients with schizophrenia." *International Journal of Geriatric Psychiatry*. 28(12): 1305:11.

[5] Joshi K, Lin J, Lingohr-Smith M, Fu D-J, Muser E. 2016. "Treatment patterns and antipsychotic medication adherence among commercially insured patients with schizoaffective disorder in the United States." *Journal of Clinical Psychopharmacology*. 36(5): 429.

3. Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer: This measure combines the rates of the previous two measures: individuals receiving prescriptions for opioids with a daily dosage greater than 120 MME for 90 consecutive days or longer, AND who received opioid prescriptions from four or more prescribers AND four or more pharmacies.

The details of the first and third measures are misaligned with the 2016 Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain. We recommend aligning these quality measures with others recently open for CMS public comment, reflecting the CDC guideline recommendations that specify "90 consecutive days with high-dose usage is defined as at least 90 milligrams morphine equivalent dosage per day."

We are extremely concerned that the modifications to all of the measures in this measure set would exclude patients prescribed buprenorphine for the treatment of opioid use disorder (OUD). We urge CMS to withdraw this modification. Patients receiving buprenorphine for MAT could also receive separate prescriptions for opioids for pain management after procedures or for other conditions, particularly from providers who may be unaware of the MAT. Buprenorphine blocks the therapeutic effects of other opioids. Because of this neurochemical complication, opioids prescribed for those who are also treated with MAT-indicated buprenorphine will not be as effective as for other patients, and their pain will not be relieved, regardless of the prescribed dose. Patients receiving opioids for pain may also become noncompliant with their MAT. Both situations increase the risk of an opioid overdose for these patients. Providers need to be aware of this possibility so that these patients can be closely monitored. Consequently, these patients should be included in this measure.

Potential New Measures for 2020 and Beyond

Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions: Given the high rates of patients with mental health disorders and medical comorbidities, this measure attempts to close the gap related to breaks in care. The APA supports the goal of improving ongoing and continuous psychiatric and medical/physical care, which can positively impact patient outcomes. However, we reserve our opinion of this measure for addition for 2020 and beyond. We request that the measure specifications include a well-defined attribution model that will appropriately assign the measure action and related outcomes to the appropriate provider (impacting the health plan payments). We also have concerns about the source of the data informing the quality of care administered in this measure. In particular, collecting this data through claims would be problematic. International Classification of Disease (ICD) coding does not allow psychiatric conditions to be the primary diagnosis when beneficiaries arrive in an emergency department with physical symptoms (e.g., overdose, lacerations, etc.) resulting from a suicide attempt. Therefore, it would be difficult to accurately capture data to track appropriate follow-up psychiatric care.

Opioid Overuse: The plan by the National Committee for Quality Assurance (NCQA) to develop a measure that addresses health plan members who were previously "naïve" to opioids who become long-term or "chronic" users is interesting. Considering the national opioid epidemic, it is a subject deserving of quality measure development. However, since the details of this measure and the specifications are under refinement, we are uncertain why determining the definitions of "opioid naïve" and "chronic use" would impact and improve the quality of care at

the health plan level. If NCQA were to move forward and develop this quality measure, we would be e interested in reviewing the rationale, the specifications, and the test data.

Measure Concept: Concurrent Prescription of Opioids and Central Nervous System (CNS) Depressants: NCQA's consideration in testing this measure concept will aid in monitoring unsafe prescribing practices or prescriber error. As with the other measures previously described being considered for development, the APA reserves supporting them until the specifications, test data, and other appropriate details that promote development of this measure are shared. We request a close examination of potentially harmful unintended consequences that could negatively impact the patient and the prescriber. Understanding that this is being developed to measure the quality of care at the health plan-level, we understand that it also impacts direct care provided at the physician level. We also request that data sources used to measure concurrently prescribed medications appropriately illustrate the provider-patient encounter. There could be justifiable therapeutic rationale behind the practice, and it should not be assumed that concurrent prescriptions automatically point to poor care.

Assessment of Care for People with Multiple High-Risk Chronic Conditions: This measure includes modifications to an existing measure used in other programs, and now is under consideration for potential use by MA plans. The modifications expand from four indicators (medication review, functional status, pain assessment, and advanced care planning) to six (physical assessment, cognitive functioning, pain assessment, fall risk assessment, goals of care discussed, and advanced care planning). We will be very interested to learn how the two additional indicators would enrich the data. Due to the provision of limited details on these measure updates, the APA reserves support for measure implementation until testing is finalized and that data is shared. We also suggest this measure specify the use of standardized evaluative tools. The APA questions the value of including follow-up measures linked to the indicators that address functional, cognitive, pain, and care goals. While these measures are intended to demonstrate quality at the health plan-level, it is the performance of the clinicians and the outcomes of patients that is being monitored.

Depression Screening and Follow-Up for Adolescents and Adults: This measure was adapted from the provider-level measure. It examines the percentage of patients age 12 and older who were screened for depression using a standardized assessment tool (such as the PHQ-9) and if positive, whether they received appropriate follow-up care within 30 days. As the measure is currently specified at the provider level, it presents a list of standardized screening tools recommended for use but does not mandate that measure users are limited to the tools listed. The APA is interested in learning how the measure specified this way allows for robust national results at the plan level, and whether plans would specify which tool should be used to collect this information.

Unhealthy Alcohol Use Screening and Follow-Up: NCQA adapted this plan-level measure from a measure originally specified at the provider-level. The APA is interested in viewing the testing data of this measure to determine appropriateness at the plan-level. Given the choice to use one of several standardized screening tools to satisfy this measure, the APA is interested in learning how the measure, as specified, would provide robust national results at the plan level.

Readmissions from Post-Acute Care: NCQA plans to develop a measure that evaluates acute care facility readmissions among Medicare beneficiaries during or after a skilled nursing facility (SNF) stay. Like other measures

included in this Draft Call Letter, the APA does not support the measure at the present time. However, given the concerns we have previously voiced to CMS, this measure could help examine the effects of broad, sweeping limitations (imposed by CMS) on psychotropic prescribing practices for patients in SNFs and other long-term care settings. Acknowledging this possibility, the APA supports further development and testing at the plan level and possibly the facility level.

Anxiety: NCQA is considering developing HEDIS (Healthcare Effectiveness Data and Information Set) quality measures that assess care for those with anxiety disorders. While limited details are available on this measure (set), measuring this diagnostic condition does align with APA priorities. Given its prevalence in mental health specialty care settings, among others, this measure could have benefits at the primary care settings. As such, the APA would be interested in learning more as the measure is further considered for development.

We welcome the opportunity to discuss these issues further. If you have any questions, or if we can be of further assistance, please contact Debra Lansey, M.P.A., APA Associate Director for Payment Policy, at DLansey@psych.org or (202) 609-7123.

Sincerely,

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