AMERICAN PSYCHIATRIC ASSOCIATION

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

December 31, 2019

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

Re: Medicare Program; CY 2020 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 Professionals; 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 Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule

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 interim final rule on the provision of self-administered esketamine, which is contained within the final rule on the 2020 Medicare Physician Fee Schedule and Quality Payment Program.

Our members are frontline specialists in the medical treatment of Medicare beneficiaries with mental illness. They prescribe psychotropic medications and provide a range of services including psychotherapy, TMS, and ECT for patients with mental health and substance use disorders. Psychiatrists practice in all settings and are at the forefront of research into the sources of and new treatments for mental illness, especially those involving psychotropic medications.

As CMS notes in the final rule of the 2020 Medicare Physician Fee Schedule, Spravato™ (esketamine) nasal spray was approved for use in March 2019, by the U.S. Food and Drug Administration (FDA) in conjunction with an oral antidepressant for patients who have tried but failed to respond to at least two courses (of adequate dosages and durations) of antidepressant medications. Further, the FDA mandated that Spravato™ be available only through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS) due to the risk of serious adverse reactions and the potential for abuse or misuse.

Associated adverse reactions are known to include sedation, dissociation, and increased blood pressure;[1] as well as nausea, dizziness, vertigo, and headaches.[2, 3]

The REMS drug safety program requires individuals or entities that want to purchase the product for distribution, dispensing, or supervision of administration to enroll and be certified by the Spravato™ REMS program. All patients who are administered the medication must also enroll in the REMS program before they can receive the medication. The REMS program requires that the patient self-administer the medication under direct observation of a healthcare professional and that the patient remain and be observed for at least two hours post-administration. Any adverse reactions are to be reported via the Spravato™ REMS drug safety program.
In the final rule CMS states that "it is in the public interest to ensure appropriate patients have access to this potentially life-saving treatment." It goes on to acknowledge that there is no existing coding and payment structure that describes the services and resources required to administer the medication and that, considering this lack, they have created two HCPCS G Codes:

> G2082 (*Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation*); and
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> G2083 (*Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation*).

In determining the interim final values for these codes, CMS used a building block methodology, using the values of several established codes:

> 99212 (*Office or other outpatient visit of the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; a problem focused examination; straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problems(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*);

[1] FDA Briefing Document Psychopharmacologic Drugs Advisory Committee (PDAC) and Drug Safety and Risk Management (DSaRM) Advisory Committee Meeting. (2019, February 12). Retrieved from https://www.fda.gov/media/121376/download

[2] Popova V, Daly EJ, Trivedi M, et al. Efficacy and Safety of Flexibly Dosed Esketamine Nasal Spray Combined with a Newly Initiated Oral Antidepressant in Treatment-Resistant Depression: A Randomized Double-Blind Active-Controlled Study. American Journal of Psychiatry 2019 176:6, 428-438

[3] Fedgchin M, Trivedi M, Daly EJ, et al. Efficacy and Safety of Fixed-Dose Esketamine Nasal Spray Combined with a New Oral Antidepressant in Treatment-Resistant Depression: Results of a Randomized, Double-Blind, Active-Controlled Study (TRANSFORM-1). Int J Neuropsychopharmacol. 2019;22(10):616–630. doi:10.1093/ijnp/pyz039

99415 *(Prolonged clinician staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour (list separately in addition to code for outpatient Evaluation and Management service))*;

99416 *(Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision, each additional 30 minutes (List separately in addition to code for prolonged service));* and

The Wholesale Acquisition Cost (WAC) of the medication based on the cost data from the most recently available quarter.

APA Recommendations

APA supports CMS's decision to provide coverage for this service, which offers Medicare beneficiaries suffering from treatment resistant depression an alternative treatment that has been shown to have had a positive impact on patients' mental health. Given that this requires a new way of delivering medication, there is likely to be initial variability in the field, which supports the need for flexibility in the way the services are reported. Creating a payment structure that limits coverage or is insufficiently valued will impede access to this medically necessary treatment.

The way the bundled payments are currently constructed fails to recognize the possible variability of E/M services that may be required, the time and effort required of clinical staff to monitor the patient during the lengthy observation period, and the amount of pre- and post-service work required. We also have concerns that the bundled payment structure will be problematic because of emerging trends within in the commercial insurance plans.

Bundled payment and valuation

We recommend unbundling all the services as well as the cost incurred to purchase the medication. Bundling together the physician E/M service and the observation services performed by clinical staff is problematic because they are separate and distinct services and are not always jointly required. Including the medication in the bundle is also problematic because in many instances the psychiatrist may not be incurring the cost of the medication.

Variability in the performance of and level of E/M services: Feedback from our membership indicates that a face-to-face visit with the psychiatrist is not required at each visit. There are, however, clinical decision points over the course of care that necessitate direct physician involvement. The 99212 E/M service (99212 (*Office or other outpatient visit of the evaluation and management of an established patient…Usually the presenting problems(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*)) used to calculate the valuation of the bundle does not adequately reflect the range of physician services provided when a face-to-face visit with a psychiatrist occurs. Patients receiving esketamine treatment are psychiatrically complex, having previously failed at least two courses of different medications. The REMS requirement reflects the risks associated with the medication, including the potential for serious side-effects and the potential for abuse and misuse of the medication. The range of E/M work provided by psychiatrists includes reviewing the treatment

process, risks and benefits, and responding to patient questions at the first treatment session; evaluating the effectiveness of the medication throughout the course of care; and addressing known side-effects from nausea and vomiting to hallucinations (as well as any new ones that may occur) over the course of the two-hour monitoring period. On any one of the visits to administer the drug, the patient's presentation could require a higher level of E/M service than the minimal 99212 included as part of the bundle. **We recommend allowing for the appropriate billing of the E/M work as a separately billable service, when performed.**

Clinical staff time and accounting for all activities: Clinical staff time and effort comprise a significant and separate service. This new service includes not only the time spent observing and actively monitoring the patient's condition for possible adverse side-effects (i.e., nausea, vomiting, escalation in blood pressure), but also extensive pre- and post-service preparation that does not appear to have been included as part of the bundled payment and is not described by existing CPT codes. This includes:

- Time and effort of clinical staff spent fulfilling the requirements of the REMS program, including registering individual patients, separately documenting each treatment session, and recording any adverse events as they occur into the REMS program, all of which is in addition to the standard documentation of the visit;
- Time spent navigating the prior authorization process to secure approval to proceed with the prescribing of the medication;
- Time spent ordering the medication from the REMS-certified pharmacy, which must be done on a per patient basis. The limitations on the amount of medication that can be ordered at any onetime results in the need to contact the pharmacy multiple times over the episode of care; and
- Added expenses to ensure safe storage, preparation, and disposal of a controlled substance.

Overall valuation of the observation and pre- and post-service work of the clinical staff: We recommend increasing the proposed valuation of clinical staff time to more appropriately account for the clinical staff time and the effort required for pre-, intra-, and post- service work. This includes acquisition of the drug, delivery of the medication to the patient, and the observation of the self-administration, followed by active monitoring of the patient's condition (vitals, etc.) for a minimum of two hours. Higher doses, which require repeated administrations, and medical complications both require extended observation. This procedure is separate from any E/M work that may occur on the same date of service. The extensive pre- and post-service work and the possibility of lengthier observation periods do not appear to have been factored into the proposed payment.

Recognition of the additional pre- and post-service work of clinical staff

The standard clinical activities that occur at each visit (i.e., greeting the patient and ensuring the appropriate medical records are available, obtaining baseline vital signs, preparing the room (equipment and supplies), and documentation of the visit and follow up with the patient post-procedure), as well as additional clinical staff time spent fulfilling the requirements of the REMS program (separate documentation and reporting for each visit) should be accounted for in the valuation of this clinical staff service. There should also be recognition of additional activities that are a required part of each visit, such as the ordering, safe handling/preparation, storage, and disposal of a controlled substance.

This level of activity, which is separate from the time spent actively monitoring the patient, falls between the clinical activities of the 99211, *Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.* (19 minutes intra-time; Practice Expense (PE) RVU 0.46), which is the standard components of an E/M service that does not require the presence of a physician and the clinical staff time of the 99212, *Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family.* (28 minutes of intra-service time; PE RVU 0.75).

Increase the valuation of the observation period: CMS chose code 99415 (*Prolonged clinician staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour (list separately in addition to code for outpatient Evaluation and Management service)*) (15 minutes intra-service time; PE RVU 0.28) and add-on code, 99416 (*Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision, each additional 30 minutes (List separately in addition to code for prolonged service)*) (8 minutes intra-service time; PE RVU 0.12) as the comparison codes in the building-block approach to the creation of the G2082 and G2083. These codes are meant to be used in conjunction with an E/M service to account for additional non-continuous work of clinical staff beyond the typical E/M visit. These codes are billed in increments of time and cannot be billed for more than two patients simultaneously. The new esketamine observation service is a discrete and separate procedure, with a variety of pre- and post-service activities related to the REMS and intra-service activities related to the observation and active monitoring of patients, and may or may not be accompanied by an E/M. As such, it is more appropriate to compare this new service to an existing service that is structured in this way.

The more appropriate comparison for the clinical staff time related to the two hour observation period is 95076, *Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug or other substance); initial 120 minutes of testing* (110 minutes intra service time; PE RVU 1.81). Both services, the G2082 and G2083 codes and the 95076, require a lengthy observation time (minimum of two hours) with clinical staff monitoring for adverse side-effects. The total PE RVU of the 95076 is 1.81 RVUs versus 0.51 RVUs (99415 x 1, 99416 x 2 or 0.27 + (0.12 x 2) = 0.51 RVUs) of the combined 99415 and 99416. The associated add-on code for 95076 is 95079, *Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug or other substance); each additional 60 minutes of testing (List separately in addition to code for primary procedure)* (40 minutes intra-service time; PE RVU 0.99) which would account for additional time for this service when required. **Procedurally these services are similar in staff time, staff type and effort, and both are reported separately from the E/M service.**

We note that this falls below the 96365 (Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour (PE RVU 1.74 and time 46 minutes) and 96366 (Intravenous infusion, for

therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure) (PE RVU 0.42 and time 12 minutes)) (total PE RVU of 2.16 when both are billed together) which are similar in staff time, staff work (periodic patient assessment with vital sign monitoring) and special handling and disposal of controlled substances to the G2082 and G2083 codes.

The 95760 falls above the 96360 (Intravenous infusion, hydration; initial, 31 minutes to 1 hour (PE RVU 0.77 and time of 18 min) and 96361 (each additional hour (List separately in addition to code for primary procedure) (PE RVU 0.28 and time of 9 min) (that has a total PE RVU of 1.05 when billed together) which require less monitoring and no special handling procedures.

We request that CMS use the practice expense RVUs for the 95076 and the 95079 in lieu of the 99415 and 99416 in the calculating the values for the clinical staff component. This will more accurately reflect the time and effort of the clinical staff in the observation of the patient.

Option to bill for additional time beyond the minimum 120 minutes: As stated above our members have reported that many patients are requiring observation longer than the two-hour minimum because of side-effects (blood pressure elevation or ongoing nausea). It is also notable that when a patient's dose is 3 vials (84mg), the patient must wait 5 minutes between each dose, which adds additional time. **The ability to bill for additional observational time, as necessary, is also recommended.**

We encourage CMS to create HCPCS codes that account for the entirety of the time and effort spent by clinical staff on the required face-to-face and non-face-to-face services, and that they be valued appropriately. This should include a code to account for additional monitoring time. Using the building block methodology, the PE valuation for the clinical staff activities should be no less than the PE values for the 99211 and 95076 or 0.46 plus 1.81 for a total PE RVU of 2.27 for the base code (excludes the medication). And the add-on code would be valued similarly to the 95079 at 0.99 RVUs for additional observation.

The cost of the medication: CMS has bundled the cost of the medication into the payment under G2082 and G2083 and has advised that physicians should bill existing CPT codes in those instances where they are not incurring the cost of the medication. This is problematic for several reasons. In developing the bundle CMS has acknowledged that the current CPT codes do not accurately capture the work required. Additionally, payment policies of private payers vary. A number of plans are covering the medication separately under the patient's pharmacy plan, which means there could be a sizable number of psychiatrists who will be forced to bill outside of the bundle. As a result, there is a significant concern that the reimbursement received through the ad hoc billing of CPT codes, which do not adequately describe providing esketamine treatment, will not be sufficient to cover the cost of care. This is further compounded by the fact that not all payers cover all services, such as the prolonged service codes. **We recommend CMS allow for the billing of the cost of the medication separately.**

Clarification

The preceding comments focus primarily on the work associated with care provided in the office/outpatient setting. The rule lacked clarity as to the inputs used to develop the payment in the facility/facility-based

outpatient program. We ask that CMS both **clarify the inputs used in the development of the facility payment and apply appropriate changes to the valuation based on the recommendations above**.

Should CMS move forward with the bundled payment, we would like to know if CMS will update those values based on future changes to the valuations that underpin the payment? For instance, the outpatient E/M values are set to increase in 2021, will that increase automatically be included in the valuation of the bundle? Will the payment currently ascribed to the bundle for the cost of the medication be updated if the price changes over time?

Summary of recommendations

In conclusion, we support CMS's decision to provide coverage as quickly as possible for treatment with esketamine to give Medicare beneficiaries access to a new, effective evidence-based treatment. However, we urge CMS to reconsider the proposed structure and valuation, which we believe will limit access to the treatment. We recommend that CMS unbundle the services -- the E/M services provided by a physician; the clinical staff time, which includes the procurement of the medication, administration and observation/patient monitoring; and the cost of the medication - and allow for billing of each separately. We ask that CMS appropriately account for and value all clinical staff activities (both face-to-face and non-face-to-face) based on CPT codes 99211 and 95076 with add-on code for additional time, 95079, discrete services that are similar in time and effort. Using the building-block methodology, the valuation would be no less than 2.27 PE RVUs for the base code and no less than 0.99 PE RVUs for the add-on code used to describe additional time. This requires the addition of two new HCPCS codes that describe the clinical staff activities during each visit, including the initial period of observation and an additional add-on code for those times the initial observation period is prolonged. We understand that billing for the medication separately would require the implementation of a HCPCS code specific to the approved medication, but this is necessary to provide realistic coverage for this treatment.

Thank you for your ongoing support for care to those diagnosed with mental illness or substance use disorders. Please contact Becky Yowell (byowell@psych.org), Director of Reimbursement and Quality, with any questions.

Sincerely,

Saul Levin, MD, MPA
CEO and Medical Director
American Psychiatric Association