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Assembly 2024-2025

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Administration Marketa Wills, M.D., M.B.A. CEO and Medical Director September 9, 2024

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

Re: File Code CMS-1809-P

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

Dear Administrator Brooks-LaSure:

The American Psychiatric Association (APA), the national medical specialty society representing more than 38,000 psychiatric physicians and their patients, would like to take the opportunity to comment on the hospital outpatient prospective payment system and quality reporting programs.

We appreciate the Administration's commitment to supporting our nation's mental health through increasing the capacity of services, connecting more people to care, and attending to an environment that supports health and mental health. Our comments focus on supporting evidence-based treatment for mental health and substance use disorders through coverage and reimbursement and ensuring proposed quality measures are meaningful.

Changes to the List of ASC Covered Surgical Procedures and Ancillary Services Lists

APA urges CMS to reconsider their decision to not add electroconvulsive therapy (ECT) (90870 -a bundled payment that includes 00104), to the ASC covered procedures list (ASC-CPL). ECT meets the general standards for ASC settings in that it does not pose a significant safety risk to Medicare beneficiaries when performed in an ASC, and the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. The general <u>exclusions</u> defined by CMS do not apply nor the exclusions found at <u>§ 411.15</u>. In 2019, CMS expanded the eligibility criteria for ASC CPL consideration to include services that are a direct "crosswalk or are clinically similar to procedures in the Category I CPT code surgical range."

While not defined as a surgical procedure (CPT codes 10000 - 69999), **ECT is "clinically similar"¹ to other procedures routinely performed in an ASC such as colonoscopies and upper endoscopies.** The patient is under anesthesia, the procedure is minimally invasive (i.e., no skin is broken other than for an IV), and the patient can return home that day, usually returning home about an hour after the treatment.² Any procedure suite with appropriate equipment and monitoring capabilities for general anesthesia and anesthetic recovery would be a safe setting for ECT. Furthermore, the equipment needed to deliver ECT could be easily stored and maintained, along with necessary supplies, in an ambulatory surgery location.

The patient flow and sequence of clinical activities that are involved in administering outpatient ECT are very similar to those associated with other brief procedures that are performed in an ASC. Patients are first evaluated by a psychiatrist to determine whether ECT is an appropriate treatment for them. As part of the evaluation, the psychiatrist identifies whether additional assessments are needed such as laboratory studies or specialist consultations in the same way that such assessments might occur prior to other procedures. For each patient, the psychiatrist also determines whether ECT is appropriate to administer on an outpatient basis or whether inpatient admission is needed, either for psychiatric or medical reasons. For individuals treated as an outpatient, the patient refrains from eating or drinking prior to the procedure and, after a typical check-in process, is taken to a pre-procedural area. The psychiatrist, anesthesiologist, and nursing staff do a pre-procedural assessment and verify that informed consent has been provided. The nursing staff prepare the patient, including inserting an intravenous catheter for administering fluids and anesthetic medications. A pre-procedural "time-out" is conducted and monitoring electrodes are placed to assess vital signs, cardiac rhythm, and oxygenation status, as is typical for procedures that require general anesthesia.

After administration of an anesthetic agent and a muscle relaxant by the anesthesiologist, the psychiatrist delivers a brief electrical stimulation through small electrodes placed on the head. The resulting electrically-induced seizure is monitored using electroencephalography and typically lasts about a minute. Motor movements associated with the seizure are minimal because of the use of a short-acting muscle relaxant as part of the anesthesia. When the anesthetic medications wear off, typically within a few minutes after the procedure, the patient resumes spontaneous respirations and can be moved to the recovery area. While there, they continue to be monitored by recovery nursing staff who assess vital signs, cardiac rhythm, patient comfort, alertness, and other parameters, as would

¹ Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements; Final Rule. Vol Vol. 86, No. 221.; 2021.

² American Psychiatric Association. Updated January 2023. Accessed September 5, 2024. https://www.psychiatry.org/patients-families/ect

be required for any procedure involving general anesthesia. Once the patient is alert, they are offered fluids and food as appropriate.

Standard post-anesthetic criteria are used to determine when the patient can be discharged from the recovery area to return home. While the patient is in the recovery area, the psychiatrist remains in the building and immediately available to address any issues that may arise. These most often relate to symptomatic treatment for agitation, nausea, or headache. Increases in blood pressure or heart rate can occur but typically resolve spontaneously. It is rare for a patient to have a prolonged stay in the recovery area or require admission for medical stabilization. If admission to a psychiatric service were needed, based on the evaluation by the psychiatrist at the time of the ECT, this would be arranged through the typical processes for psychiatric hospitalization of an outpatient and would not require staying in the ASC. *Thus, the processes related to ambulatory administration of ECT are clinically similar to those of other brief procedures involving administration of general anesthesia.*

Additionally, as stated in prior requests and our recent meeting with CMS, ECT is widely viewed as the most efficacious treatment available for severe mood disorders. Despite this, over recent decades hospitals have become less likely to offer ECT.^{3,4,5,6} Access to ambulatory (outpatient) ECT continues to decline.⁷ This has occurred in tandem with reductions in the lengths of hospital stays and reduced access to inpatient psychiatry care, in general, but particularly in rural areas. Limiting ECT to hospital settings can effectively eliminate access to outpatient or maintenance ECT for patients in rural areas due to lengthy travel times needed to reach a hospital that offers ECT. The fact that ECT is administered as a series of treatments, typically three treatments weekly for two to four weeks for an acute treatment course and weekly to monthly ECT for maintenance treatment, adds to the travel burdens for patients and friends, family, or other caregivers who must drive them to and from the procedure.

Better access to ambulatory ECT not only improves patient outcomes but has been shown to reduce hospital admissions and readmissions.⁸ Adding ECT to the list of procedures that can be performed in an ASC not only expands access to an effective mental health treatment but also aligns with CMS's commitment to improving healthcare outcomes and access for patients with psychiatric conditions.

³American Psychiatric Association: The practice of electroconvulsive therapy: recommendations for treatment, training, and privileging (A task force report of the American Psychiatric Association), Third Edition. Washington, DC, American Psychiatric Association, 2025.

⁴ Karl S, Schönfeldt-Lecuona C, Sartorius A, Grözinger M. Provision of Electroconvulsive Therapy During the COVID-19 Pandemic: A Survey Among Clinics in Germany, Austria, and Switzerland. J ECT. 2022 Sep 1;38(3):205-210. doi:

^{10.1097/}YCT.00000000000846. Epub 2022 Apr 14. PMID: 35462387; PMCID: PMC9426313.

⁵ Demchenko I, Blumberger DM, Flint AJ, Anderson M, Daskalakis ZJ, Foley K, Karkouti K, Kennedy SH, Ladha KS, Robertson J, Vaisman A, Koczerginski D, Parikh SV, Bhat V. Electroconvulsive Therapy in Canada During the First Wave of COVID-19: Results of the "What Happened" National Survey. J ECT. 2022 Mar 1;38(1):52-59. doi: 10.1097/YCT.0000000000000000801. PMID: 34519681; PMCID: PMC8875437.

⁶ Maixner DF, Weiner R, Reti IM, Hermida AP, Husain MM, Larsen D, McDonald WM. Electroconvulsive Therapy Is an Essential Procedure. Am J Psychiatry. 2021 May 1;178(5):381-382. doi: 10.1176/appi.ajp.2020.20111647. PMID: 33979536.

⁷ Slade EP, Jahn DR, Regenold WT, Case BG. Association of Electroconvulsive Therapy With Psychiatric Readmissions in US Hospitals. JAMA Psychiatry. 2017;74(8):798-804. doi:10.1001/jamapsychiatry.2017.1378

⁸ Ibid.

APA requests that CMS reconsider our application to include ECT on the ASC CPL. If CMS chooses to maintain their position and not include the service, we ask that CMS communicate their rationale, noting the specific criteria, to APA or within the Final Rule.

New Technology Ambulatory Payment Classification (APCs)

Depression is common, and as many as one-third of people with depression are considered treatment resistant, which is defined as those individuals who have not found relief from symptoms of depression even after trying several antidepressants. Esketamine (G2082 and G2083), and Transcranial Magnetic Stimulation (TMS), including accelerated iTBS ("accelerated TMS"), (0890T, 0891T and 0892T), expand the treatment options available for patients suffering from TRD beyond traditional interventions, such as ECT, and affords psychiatrists the opportunity to consider a wider range of treatment options based on patient profile and response to treatment. It is important to ensure that Medicare beneficiaries have access to care that improves their condition and reduces long-term costs of untreated or undertreated illness.

We are concerned that the New Technology APC rates for these critical interventions are not sufficient to cover the costs of providing these interventions. This could significantly limit the ability for patients with TRD to have access to care that has been shown to be safe and effective. In the case of accelerated TMS (0890T, 0891T and 0892T), hospital outpatient settings are well positioned to provide this care, however APC 1522 does not adequately reflect the resources required to perform these services in that setting. Inadequate payments and the disparity in payments between inpatient and outpatient settings for accelerated TMS could have a chilling effect to the point that care provided in the hospital outpatient setting will no longer be viable, pushing patients to the inpatient setting for their care. This will limit, and in some cases, eliminate the availability of this intervention for Medicare beneficiaries. We urge CMS to reassign the New Technology APC assignment for accelerated TMS (0890T, 0891T and 0892T) to New Technology APC 1528. This more appropriately reflects the resources required to perform the interventions, ensuring access to evidence-based care.

Cross-Program Proposals for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs

APA applauds CMS's commitment to addressing health equity in its quality and measurement programs and attempting to align the measures among reporting programs. Identifying health disparities and addressing gaps in care are vitally important goals, and we support efforts to find the most useful and appropriate methods for collecting data on disparities and social determinants of health. **We urge CMS to prioritize measuring conditions where there are identified disparities in treatment or outcomes;** this will allow CMS to bring attention to inequities in these areas and incentivize institutions to improve. CMS has proposed three health equity measures:

- Hospital Commitment to Health Equity (HCHE) Measure and/or the Facility Commitment to Health Equity (FCHE)
- Screening for Social Drivers of Health Measure
- Screen Positive Rate for Social Drivers of Health Measure

APA is concerned that none of these measures have been fully tested or validated specifically for the outpatient, rural emergency, or ASC care settings. Testing is critical to understanding if the proposed measure leads to improved patient outcomes and the feasibility of implementing the measure in this setting.

Proposal To Adopt the Hospital Commitment to Health Equity (HCHE) Measure for the Hospital Outpatient Quality Reporting (OQR) and Rural Emergency Hospital Quality Reporting (REHQR) Programs and the Facility Commitment to Health Equity (FCHE) Measure for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

APA continues to support previous requests that CMS modify the scoring to award one point for each individual attestation rather than an all or nothing approach to the scoring in the HCHE or FCHE measures. This increases transparency and makes the measure more meaningful.

Proposal To Adopt the Screening for Social Drivers of Health (SDOH) Measure for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs

APA agrees that measuring the adoption of SDOH screening is an important first step. The next step in the evolution of measurement would be to measure if those who screen positive are connected to appropriate resources. This will be a tremendous task requiring additional financial resources and technological capabilities but will be an important step towards improving outcomes. This would be particularly challenging for rural emergency departments that may lack the resources required to monitor and track connecting patients to additional services. Furthermore, there may be limited resources in the community to which rural ED's could refer. CMS should increase funding to ensure that patients who screen positive for SDOH are able to receive resources, including things like transportation, housing, and food security. Finally, this measure allows for flexibility in the selection of the screening tool, and while that affords facilities the opportunity to select tools that best suit their environment, it risks the ability to compile and compare data in a meaningful way.

Proposal To Adopt the Screen Positive Rate for Social Drivers of Health (SDOH) Measure for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs

In its current form, a facility's performance on the Screen Positive Rate for Social Drivers of Health Measure may be impacted by social needs characteristics of the patient population being treated or community in which the facility is located. Risk adjustment must be ensured so that facilities are not penalized for having higher screen positive rates based on higher risk populations.

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

Sincerely,

APA

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