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Centers for Medicare and Medicaid Services
Attention: CMS-1678-P
P. O. Box 8013
Baltimore MD 21244-1850

Re: Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (82 Fed. Reg. 33,558, July 20, 2017)

Dear Administrator Verma:

The American Psychiatric Association (APA), the national medical specialty society representing over 37,000 psychiatric physicians and their patients, would like to take the opportunity to comment on the 2018 proposed rule for the Medicare Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Centers (ASCs). Our comments focus specifically on issues that impact the care of patients with mental health and substance use disorders (collectively referred to as “behavioral health” disorders), particularly:

- Suggestions for the Hospital Outpatient Quality Reporting Program, including the importance of appropriate risk adjustment and developing a standardized definition of “topped out” measures across the diverse array of quality programs for Medicare and other payors;
- Adding additional search engines to Hospital Compare, to allow consumers to access all appropriate providers; and
- Increasing patient access to electroconvulsive therapy (ECT) through Medicare coverage of ECT when performed in ambulatory surgical centers.

HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

Hospital Outpatient Quality Reporting Program

APA welcomes the opportunity to comment on the Hospital Outpatient Quality Reporting (OQR) Program. We strongly support the programmatic goals of improving patient outcomes at the facility level. Like other CMS quality payment programs, the Hospital OQR Program mandates that hospitals providing outpatient services must either meet administrative, data collection, data submission, validation, and publication requirements, or else receive a percentage-point reduction in their annual payment update.

Social Risk Adjustment in the Hospital Outpatient Quality Reporting Program

APA applauds CMS's effort to align its multiple quality payment programs when accounting for social risk factors. For application to the Hospital OQR Program, CMS asks which social risk factors might be most appropriate for reporting stratified measure scores, as well as potential risk adjustment of a specific measure. The APA encourages appropriate risk adjustment for certain variables, such as social risk factors and socio-economic status (SES). This can prevent penalties and disincentives for providers who see a higher proportion of the sickest and most economically disadvantaged patients, who often need the most help. Risk adjustment can also counter inaccurate presumptions that psychiatric inpatient readmissions and other negative patient outcomes always stem from the patient receiving bad care.

However, there are several limitations in the currently available data sources from which these risk-related variables are extracted, including the absence of sufficient indicators of psychosocial complexity that would allow exploration into how quality can vary based upon these factors.

The APA supports the inclusion of risk adjustment in quality measurement for psychiatric settings. We look forward to the results of the two-year risk adjustment measure testing project directed by the National Quality Forum (NQF), to help inform how to best capture this information. Considering the current climate and the ability to reliably capture certain social risk factors, this could have a positive effect for patients with behavioral health issues. It could prevent stand-alone psychiatric hospitals and outpatient psychiatric units and facilities from being unfairly penalized for treating higher risk patients. Regarding the concerns over electronic health record (EHR) discrepancies, it is unlikely that the information collected at the point of care, or from billing, would adequately include information that would display the full picture of the patient or the quality of care provided. However, **the APA also recommends vigilant examination and identification of any potential, unintended consequences that may result from the application of risk adjustment, when stratifying by SES, by psychiatric condition acuity level, or by insurer.** We invite CMS to engage in discussions with APA member experts to identify a comprehensive process that would positively impact behavioral health patients, clinicians, and facilities.

Hospital Outpatient Quality Measure Retention and Removal

The APA supports CMS's general policies regarding removal and retention of quality measures for this and other Medicare quality reporting programs. However, **CMS's description in this proposed rule of a "topped out" measure does not hold true for all public and private quality programs.** "Topped out" measures are defined by indistinguishable performance at the 75th and 90th percentile, i.e., measures that are consistently achieving success by nearly all participants. There are wide-reaching efforts by multiple entities involved in quality measurement (e.g., CMS, NQF, Physician Consortium for Performance Improvement, National Committee for Quality Assurance, Agency for Healthcare Research and Quality, etc.) to *align* and *harmonize* quality measures and their reporting programs. It would also be very helpful for these leading quality organizations to arrive at a consensus on a consistent, standard definition of a "topped out" measure. Moreover, automatically removing a quality measure as "topped out" based merely upon how often it is successfully reported—without examining why this is occurring—can be very detrimental to both the program and the patients that it serves.

For instance, when the reporting rates of a process measure show that its users are in the 75th to 90th percentile for compliance, this could be attributed to the fact that the quality measure is actively being measured (“what gets measured, gets done”). Naturally, retiring a “topped out” measure from a quality performance program is likely to result in a decline of what is being measured. This is a real problem when the process being measured contributes to positive health outcomes. It is also possible, due to the inherent design of certain EHR systems, that some automatically report compliance with certain quality measures, such as automatically completing required EHR fields for screening or counseling for tobacco dependence. **APA recommends that CMS further examine the definition and mechanisms that assist in determining a measure is “topped out,” before arbitrarily assigning this status and summarily retiring quality measures that support and contribute to quality patient care.**

Publication of Results on Hospital Compare

APA supports CMS’s goal of helping Medicare beneficiaries make more informed health care decisions and we understand the need to publish data gathered from the Hospital OQR Program on Hospital Compare. **However, we have concerns with how the data is presented on Hospital Compare.** The search options are limited to searching by patient location. **We recommend also offering search boxes allowing searches by medical specialty and keywords.** This is particularly important as there are facilities that accept Medicare and provide outpatient or emergency services, but cannot be found on Hospital Compare by using the current “location” search method.

Similarly, because quality measures for behavioral health care are not included in the OQR Program, data illustrating the degree of quality for behavioral health care are not published on Hospital Compare. Consequently, it is unclear how consumers view facilities providing behavioral services when they are attempting to use quality data to select an outpatient facility. This lack of information could mislead consumers to interpret that poor quality of care is provided at a given facility, when in fact that given facility provides excellent care. **APA recommends that Hospital Compare developers provide more descriptive information about the facilities that lack information about quality measurement results. APA expects that quality measures used to evaluate the provision of care at the facility level would meet the highest standards of scientific acceptability.**

Partial Hospitalization Program (PHP)

CMS reimburses partial hospitalization programs (PHPs) according to the relative weights of the four mental health ambulatory payment classifications (APCs). Reimbursement for each mental health APC is based on the geometric mean of historical hospital claims and costs for the services and other items reimbursed under that APC. The PHP regulations state that a patient is considered eligible for the benefit if they “require a minimum of 20 hours per week of therapeutic services as evidenced by their plan of care.”

In the 2017 proposed rule, CMS discussed the 20-hour requirement and asked for public comments. Meanwhile, CMS began analyzing PHP claims data from 2015 and 2016; its measurement assumption was that each documented unit of therapy equals one hour of time. The agency found that nearly half the

PHP patients received fewer than 20 hours of therapy per week, noting that some PHPs may not provide the intensive services that eligible beneficiaries need.

CMS is encouraging PHPs to review their admission practices to assure that they are providing needed services. CMS also plans to continue to consider the comments it received during the 2017 rulemaking process.

APA recommends that CMS continue to monitor the utilization of PHP service resources, and to continue providing program communications to facilities and beneficiaries, so that beneficiary access can be maintained. The agency should also consider that there are other, necessary circumstances for patients, which may interrupt a planned 20-hour service week, and which may be beyond the beneficiary's control.

Such circumstances may include job rehabilitation services, transportation issues, social rehabilitation events, and even other off-site “treatment” such as attending 12-step programs. APA expects that such events would (and should) be documented in the medical record. It is also important that providers monitor the number of patients who are not receiving 20 hours of service and develop appropriate strategies to assist these patients.

For 2018, CMS is proposing to continue to apply its established policies to calculate the PHP APC per diem payment rates, based on the geometric mean per diem costs using the most recent claims and cost data available for each provider type. For 2018 rates, the data would be from 2016. Specifically, CMS proposes to continue to use CMHC (community mental health center) APC 5853 (Partial Hospitalization [3 or More Services Per Day]) and hospital-based PHP APC 5863 (Partial Hospitalization [3 or More Services Per Day]). The CMHC or hospital-based PHP APC per diem payment rates are the national unadjusted payment rates calculated from the CMHC or hospital-based PHP APC per diem costs, after applying the OPPI budget neutrality adjustments.

CMS also proposes to apply its established “trim” methodologies in developing these per diem payment rates, including the application of a ± 2 -standard deviation reduction of costs per day for CMHCs and a CCR>5 hospital service day reduction for hospital-based PHP providers. CMS also proposes to maintain the cutoff point for outlier payments for 2018 at 3.4 times the highest CMHC APC payment rate implemented for that calendar year, which for 2018 is the payment rate for CMHC APC 5853. Additionally, the agency proposes to continue to apply the same outlier payment percentage that applies to hospitals.

APA continues to have concerns about these policies, including the consolidation of all PHP services into two APCs. We urge the agency to be vigilant in monitoring the effects of this decision to ensure that these changes to the reimbursement rates do not cause or contribute to any unintended consequences, particularly: 1) reducing the number of operational PHPs; or 2) incentivizing an otherwise unwarranted or inappropriate reduction in the number of services delivered under the single APC.

Proposed Care Management Coding Changes Effective January 1, 2018

In 2017, CMS finalized adoption of the temporary, CMS-created HCPCS codes G0502, G0503, G0504, and G0507 for the collaborative care model (CoCM) services. In this OPPS proposed rule for 2018, CMS lists four temporary, placeholder AMA CPT-created codes 994X1, 994X2, 994X3, and 99XX5. (Operationally, these placeholder AMA CPT codes will be replaced in the final rule with the permanent CPT codes for collaborative care management services.) In Table 15, CMS proposes to add 994X1 and 994X2 to ambulatory payment classification (APC) 5822, with a payment rate \$123.12. 994X3 would not be included as part of an APC, and would be a non-payable code. Code 99XX5 would be placed in APC 5821 with a payment rate \$26.67.

The APA appreciates that CMS has added the new care management codes to the OPPS schedule, as shown in the table below. These are important services to include in the agency's push towards more integrated, higher quality health care.

TEMPORARY CODE	DESCRIPTOR	APC	PAYMENT RATE
994X1	1 st psych collaborative care management	5822	\$123.12
994X2	Subsequent psych collaborative care management	5822	\$123.12
994X3	1 st /subsequent psych collaborative care	N/A	N/A
99XX5	Care management service, behavioral health condition	5821	\$26.67

Codes on the Ambulatory Payment Classification Bypass List

Over time, CMS developed a bypass list of separately paid services. The list is used to convert Medicare claims with multiple separately payable services and procedures, into claims with a single separately paid procedure that can be used for rate setting. The services on the bypass list have few associated packaged costs, and can be bypassed when assigning packaged costs on a claim to a separately paid procedure on that same claim.

For 2018, CMS proposes to update the bypass codes list with the CPT codes for psychiatric diagnostic evaluation, psychotherapy, and family and group therapies: 90791, 90832, 90834, 90837, 90846, 90847, 90849, 90853. CMS would delete obsolete psychotherapy CPT codes that are currently on the bypass codes list: 90804, 90805, 90806, 90807, 90808, 90809, 90810, 90811, 90812, 90857, and 90862. These codes were removed from the AMA's CPT code set at the end of 2012. **APA appreciates that CMS plans to update the bypass list codes for psychiatric services, allowing for more accurate payment.**

AMBULATORY SURGICAL CENTERS

CMS created a payment system specifically for one-day surgical procedures that generally do not require a patient's overnight stay in a hospital. These "ambulatory surgical centers" (ASCs) are defined as follows:

Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission . . . [ASC services means] the combined facility services and covered ancillary services that are furnished in an ASC relating to covered surgical procedures. (42 CFR § 416.2)

CMS has approved for Medicare payment in ASCs: a) procedures described within the range of Category I CPT® (Current Procedural Terminology®) codes that the CPT Editorial Panel defines as surgery; and b) services that were determined to meet the following three general criteria:

1. Do not pose a significant safety risk;
2. Would not expect to require an overnight stay when performed in an ASC; and
3. Are separately paid under the OPPI when performed in a hospital outpatient department setting.

In this proposed rule, CMS calls for public comments regarding services described by Category I or Category III CPT codes, or Level II HCPCS (Healthcare Common Procedure Coding System) codes, that may be appropriate to include as "covered surgical procedures payable when furnished in the ASC setting." CMS states "that it may be appropriate for us to use the CPT surgical range as a guide rather than a requirement as to whether a procedure is surgical, which would give us more flexibility to include "surgery-like" procedures on the ASC Covered Procedures List (CPL)."

The APA supports CMS's proposal to take a flexible approach in determining which procedures are appropriate for reimbursement when provided in ASCs. This approach can significantly increase patient access for appropriate procedures, while ensuring high quality of care and reining in costs. **We also recommend that CMS add a fourth criterion to the list above, and consider the history of a procedure's administration in the outpatient hospital setting. This would be a very appropriate additional criterion for inclusion of a particular service on the ASC covered procedures list.**

Adding Electroconvulsive Therapy (ECT) to the ASC Covered Procedures List

APA strongly recommends that electroconvulsive therapy (ECT) be added to the ASC covered procedures list (ASC-CPL). ECT has proven to be an effective therapy for patients with treatment-resistant psychiatric conditions, particularly when the patient's symptoms are life-threatening. Patient access to this crucial mode of therapy would be enhanced if ECT were added to the list of covered procedures at ASCs. Better access to ambulatory ECT may also reduce inpatient utilization given recent evidence that hospital readmissions may be reduced through appropriate use of ECT.¹ This procedure is listed in the CPT code manual as 90870 *Electroconvulsive therapy (includes necessary monitoring)*.

Description of ECT Services

Electroconvulsive therapy is an established treatment for patients with treatment-resistant psychiatric conditions and widely viewed as the most efficacious treatment available for severe mood disorders.²

ECT is most commonly used to treat individuals with severe depressive episodes, either in the context of major depressive disorder or bipolar disorder. However, ECT is also effective in other conditions including catatonia, mania, and some instances of psychosis. When a patient is experiencing acute symptoms, he or she will typically receive a course of six to 12 ECT sessions, with two to three treatments per week. Once the patient's symptoms have improved, some patients will continue to receive additional ECT treatments at a reduced frequency, to prevent the recurrence of symptoms.³

A psychiatrist performs and oversees ECT procedures as well as the related staffing, equipment, and supplies. The ECT treatment team functions as a unit and typically consists of an ECT psychiatrist, an anesthesia provider (who is privileged to deliver general anesthesia), one or more ECT treatment nurses or assistants, and one or more recovery nurses. A properly qualified ECT psychiatrist may also perform the work of the treatment nurse, or less often, the anesthesia provider. Because of the need for at least two health care professionals in the area during ECT administration, the ECT psychiatrist cannot perform all three treatment roles simultaneously.⁴ Each ASC would designate which ECT psychiatrists would receive privileges in administering ECT in that particular center.

The typical delivery of ECT services begins with the patient arriving in a hospital post-anesthesia care unit (PACU), a specialized treatment suite on or close to an inpatient psychiatric unit, or another hospital-based procedural area.

- Staff obtains indicated information about the patient's psychiatric and physical status and verifies that pre-procedural requirements have been met (such as not having taken anything by mouth after midnight, and having available transportation and supervision after the procedure).
- Other elements of care including informed consent, documentation of a history and physical, and pre-procedural "time-outs" comparable to those for other surgical and non-surgical procedures that involve administration of anesthesia.
- Intravenous access is achieved and monitoring devices are attached for assessment of the patient's vital signs, oxygenation, and cardiac rhythm.
- An anesthesia provider, typically an anesthesiologist, administers general anesthesia. Anesthesia consists of a short-acting anesthetic agent such as methohexital, etomidate, or propofol, as well as a muscle-relaxing agent such as succinylcholine. Other medications may also be administered as indicated including anticholinergic agents or medications to optimize control of blood pressure or heart rate.
- Oxygen is administered and the patient is ventilated during the time that respiratory musculature is relaxed. Intubation is rarely indicated.
- Once anesthesia and muscle relaxation are achieved, the psychiatrist administers a brief electrical stimulus through electrodes positioned on the head. Exact placement of the electrodes may vary depending on several patient-specific factors.
- The electrical stimulus induces a seizure in the brain as evidenced by electroencephalographic (EEG) tracings at the time of the treatment. Motor activity of a generalized seizure is monitored by one-lead electromyography, although the motor manifestations of the seizure are minimal.

- The duration of the electrically-induced seizure is very brief, typically 20 to 60 seconds, and the duration of general anesthesia is also short, typically about 5 minutes.
- After the patient emerges from general anesthesia and resumes spontaneous ventilation, he or she is moved to a recovery area where post-procedural oxygenation and monitoring continues under the aegis of appropriately trained nursing staff until criteria for discharge from the recovery area are met.
- For psychiatric inpatients, the individual then returns to their usual psychiatric unit. For outpatients, the individual receives instructions about follow-up care and post-procedural restrictions on activity.

Some patients may be acutely ill and meet the criteria for inpatient psychiatric treatment, such as having a significant risk of suicide or requiring continuous monitoring due to the severity of psychiatric or comorbid medical conditions. However, for many patients, it is appropriate to receive ECT on an outpatient basis if they have sufficient psychosocial support and can adhere to the requirements of ambulatory ECT. ECT has been provided in the outpatient hospital setting to Medicare beneficiaries since 2005. During that time, CMS has received over 1.5 million claims, primarily from psychiatrists and geriatric psychiatrists working in hospital outpatient departments.

Safety of Electroconvulsive Therapy

In last year's ASC final rule, CMS rejected a request to add ECT to the ASC-CPL (81 Fed. Reg. 79741), citing vague safety concerns regarding an entire list of 75 procedures and the fact that "commenters provided no specific information regarding the safety of these procedures in the ASC setting." ECT does, in fact, fulfill the CMS criteria for surgery-like procedures that can be done safely in an ASC as described in detail below.

Outpatient ECT conforms to the safety concerns that CMS has expressed in the proposed rule:

1. The beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.
2. The ECT procedure meets the ASC procedure criteria, as required by the regulations at 42 CFR § 416.166:
 - Is safely and appropriately performed in an ASC;
 - Requires resources and staff that are typically found in an ASC;
 - Does not result in extensive blood loss;
 - Does not require major or prolonged invasion of body cavities;
 - Does not directly involve major blood vessels;
 - Is not generally emergent or life-threatening in nature;
 - Does not commonly require systemic thrombolytic therapy; and
 - Is not designated as requiring inpatient care under 42 CFR § 419.22(n).

When used appropriately with indicated pre-ECT assessments, procedure-related monitoring and anesthetic techniques, ECT is very safe.⁵ In fact, ECT probably carries far fewer risks of complications than many procedures that are currently on the ASC-CPL. The ASC-CPL currently includes breast surgeries, liposuction, eye surgeries, joint repairs, and surgery for pressure ulcers. ECT is an established treatment

for patients with treatment-resistant psychiatric conditions and 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.⁶ Furthermore, substantial socio-demographic inequities exist in the ability of patients to receive treatment with ECT.⁷

In a recent systematic review and pooled analysis of international data, there were 16 reported ECT-related deaths in a total of 766,180 ECT treatments.⁸ This mortality rate of 2.1 deaths (95% confidence interval: 1.2-3.4) per 100,000 treatments was further reduced if data were limited to more recent studies, with only one ECT-related death reported in 414,747 treatments for studies since 2001.⁹ In the United States, comprehensive data is available from Texas where the rate of mortality was 2.4 deaths per 100,000 treatments within one day of ECT based upon 166,711 ECT treatments given between 1998 and 2013.¹⁰ In Veterans Administration health facilities in the United States, there were no deaths reported between 1999 and 2010 in association with 73,440 ECT treatments.¹¹

In terms of side effects of treatment, ECT is commonly associated with an increase in heart rate and blood pressure at the time of the stimulation, but these effects often resolve spontaneously.¹² If indicated, the anesthesiologist can administer medications such as beta-adrenergic blockers or other antihypertensive agents. Other common effects include nausea after the procedure, which can be managed with medications such as ondansetron, or headaches or muscle aches that can be managed with prophylactic or post-ECT administration of non-opioid pain medications. Other less common side effects (such as agitation afterwards, or increased duration of the induced seizure) can also be managed by the psychiatrist or the anesthesiologist through the administration of appropriate intravenous medications. Cognitive effects of ECT can be seen around the time of the procedure in terms of the time to become re-oriented, but these may also be evident in the days or weeks surrounding the administration of the ECT course. If significant cognitive effects do occur, this can factor into decisions about whether ECT is appropriate on an outpatient basis or not. Cautions about possible cognitive effects of ECT are also part of the instructions that are given to patients who are receiving outpatient ECT. Assessments for cognitive effects of ECT are included at the time of pre-ECT assessments and decisions may be made to adjust the ECT technique or hold ECT based on pre-procedural findings. **Thus, none of the typical side effects of ECT treatment would require ongoing monitoring or post-procedural care by the midnight following an ECT treatment.**

There are some situations in which ECT is emergent; for example, it could be due to acutely suicidal depression or prolonged immobility due to catatonia. However, these circumstances are relatively infrequent. In addition, such individuals would already require inpatient psychiatric treatment and would not be candidates for outpatient ECT, whether as a hospital outpatient or in an ASC.

It is also important to emphasize that key staff (e.g., anesthesia providers, recovery area personnel), medications, and equipment (e.g., for anesthesia administration and procedure-related monitoring) are already available in an ASC. The device needed to administer ECT is small, relatively inexpensive and could easily be housed at an ASC. Psychiatrists could travel to an ASC and have privileges to provide ECT treatment there, as is already true of other physicians who provide ASC covered procedures. Finally, ECT can be given safely in an ASC since mortality is rare, and side effects are typically self-limited, readily treatable, or can be addressed through monitoring and adjustments in treatment technique. ECT is already used safely on an outpatient basis, including outpatient use in freestanding psychiatric hospitals,

and use in an ASC would be expected to have comparable safety. **Thus, ECT satisfies all the CMS requirements for inclusion as a covered ASC procedure.**

In 2016, APA submitted written comments to the U.S. Food and Drug Administration about the safety of ECT, and requesting reclassification of the ECT device.¹³

Inaccurate, Outdated Images of ECT in Popular Culture, Versus the Current Reality

In the public media, ECT has been repeatedly portrayed as a brutal, sadistic remedy for patient non-cooperation and authority challenges. In such portrayals, ECT happens in dark scary rooms, and actors mimic extended periods of distress, painful convulsions, and seizures. In true medical practice, ECT is conducted in (primarily) hospital outpatient departments, under full *general anesthesia* and muscle relaxation, treatment lasts only a few seconds, and there is little discomfort to the patient. This outdated view of ECT, further stigmatizing mental illness, leads to the public not seeking modern day treatments. CMS can play a major role in de-stigmatizing mental illness (just as they did with new treatments and diagnostics for breast cancers, and HIV/AIDS) by ensuring that treatments supported by validated studies are paid for by CMS.

A number of online sources discuss the outdated and inaccurate images of ECT:

- How electroconvulsive therapy's troubled past has colored its modern use. <http://www.newsworks.org/index.php/local/the-pulse/101268-how-electroconvulsive-therapys-troubled-past-has-colored-its-modern-use>.
- Psychiatric Times. About to Have ECT? Fine, but Don't Watch It in the Movies: The Sorry Portrayal of ECT in Film. <http://www.psychiatrictimes.com/articles/about-have-ect-fine-dont-watch-it-movies-sorry-portrayal-ect-film>
- University of Michigan. Forget Old Movies: 9 Truths About "Shock Therapy" Today. <http://healthblog.uofmhealth.org/health-management/forget-old-movies-9-truths-about-shock-therapy-today>

Conclusion

Thank you for your consideration of these comments on these important issues. We look forward to working with you in the future to develop and implement these policies. If you have any further questions or would like the opportunity to discuss our comments, please contact Debra Henley Lansey, M.P.A., APA Associate Director of Reimbursement Policy, at DLansey@psych.org.

Sincerely,



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

¹ Slade, E.P., Jahn, D.R., Regenold, W.T., Case, B.G. Association of electroconvulsive therapy with psychiatric readmissions in US hospitals. *JAMA (Journal of American Medical Association) Psychiatry* 2017; 74(8):798-804.

² American Psychiatric Association: The practice of electroconvulsive therapy: recommendations for treatment, training, and privileging (A task force report of the American Psychiatric Association), Second Edition. Washington, DC, American Psychiatric Association, 2001.

³ *Ibid.*

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ Slade, E.P., Jahn, D.R., Regenold, W.T., Case, B.G. Association of electroconvulsive therapy with psychiatric readmissions in US hospitals. *JAMA Psychiatry* 2017; 74(8):798-804.

⁸ Tørring, N., Sanghani, S.N., Petrides, G., Kellner, C.H., Østergaard, S.D. The mortality rate of electroconvulsive therapy: a systematic review and pooled analysis. *Acta Psychiatrica Scandinavica Journal* 2017; 135(5):388-397.

⁹ *Id.*

¹⁰ Dennis, N.M., Dennis, P.A., Shafer, A., Weiner, R.D., Husain, M.M. Electroconvulsive therapy and all-cause mortality in Texas, 1998-2013. *The Journal of ECT* 2017; 33(1):22-25.

¹¹ Watts, B.V., Groft, A., Bagian, J.P., Mills, P.D. An examination of mortality and other adverse events related to electroconvulsive therapy using a national adverse event report system. *The Journal of ECT* 2011; 27(2):105-8.

¹² American Psychiatric Association: The practice of electroconvulsive therapy: recommendations for treatment, training, and privileging (A task force report of the American Psychiatric Association), Second Edition. Washington, DC, American Psychiatric Association, 2001.

¹³ March 10, 2016 Letter to U.S. Food and Drug Administration.

<https://www.psychiatry.org/File%20Library/Psychiatrists/Advocacy/Federal/APA-FDA-ECT-reclassification-comments-03102016.pdf>.