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January 23, 2018

Seema Verma, M.P.H. Administrator Centers for Medicare & Medicaid Services U.S. Department of Health & Human Services 200 Independence Avenue, SW Mail Stop 34G Washington, DC 20201

cc: Carol Blackford Director, CMS Hospital and Ambulatory Policy Group

> Kate Goodrich, MD Director, CMS Center for Clinical Standards and Quality

Eric Miranda-Marin Special Assistant, Office of the CMS Administrator

Re: CMS Policies Impacting Psychiatrists' Appropriate Inpatient Admissions, and Prescribing of Certain Medications, for Patients with Mental Health and Substance Use Disorders

Dear Administrator Verma:

The American Psychiatric Association (APA), the national medical society representing more than 37,000 psychiatrists and their patients, would like to take this opportunity to discuss some issues of particular importance to our members. These involve two current CMS policies that produce unintended consequences that interfere with (1) psychiatrists appropriately admitting patients to inpatient facilities and (2) psychiatrists prescribing certain medications for patients with mental health and substance use disorders.

I. The 2-Midnight Rule Should Not Apply to Patients with Mental Health or Substance Use Disorders

The CMS "2-Midnight Rule" has created problems for hospitals, physicians, and Medicare beneficiaries, since it was announced in the Medicare Inpatient Hospital Prospective Payment System (IPPS) final rule for 2014 (78 Fed. Reg. 50495, Aug. 19, 2013). The central idea of the Rule is that an inpatient hospital admission under Medicare Part A is appropriate only when the admitting physician expects the patient to require a stay that crosses at least two midnights. The physician (and hospital) are supposed to decide whether to admit a patient as an inpatient, based upon that analysis and expectation. CMS will reclassify as "outpatient" any stays it finds were not appropriate "inpatient" admissions. Outpatient stays are payable under the Medicare Outpatient Prospective Payment System. Reclassifying an inpatient admission as outpatient, especially after the fact, can decrease the level of Medicare reimbursement to the hospital, and increase the level of coinsurance required of the patient.

CMS established the 2-Midnight Rule to try to "right-size" hospital patient stays and discourage inappropriate or overly long inpatient admissions. Unfortunately, this policy has been problematic since its inception, for hospitals, physicians, and patients. CMS has adopted some improvements to the Rule in response to widespread criticism, but it remains an impediment to providing appropriate care for many physicians and their patients.

- Defining the minimum time period as "2 Midnights" created an arbitrary window of 25 hours, which fails to recognize appropriate inpatient stays that are even longer, but fail to span across two midnights. For example, a patient admitted at 1 AM on January 1 and discharged at 11 PM on January 3 would have an inpatient stay of 46 hours. However, because the stay did not include two midnights, it would not conform to the 2-Midnight Rule.
- The 2-Midnight Rule has created a subculture of outpatient "observation care" whereby patients are often "boarded" or otherwise spend an extended period of time in the hospital's emergency department. Other patients may be cared for on an inpatient unit but considered for billing purposes to be under outpatient "observation care," with substantial consequences in the amount of costs borne by the hospital and the patient.
- Recovery Audit Contractors (RACs) were originally charged with reviewing compliance with the Rule, and the appropriateness of inpatient admissions. The RACs often substituted their judgment for that of physicians, despite lacking appropriate expertise in the conditions that led to the admission. Fortunately, CMS has since shifted this responsibility to Quality Improvement Organizations (QIOs), which are required to have relevant expertise at the appropriate professional level.
- CMS has also amended the Rule to create a presumption that inpatient stays that do actually span two midnights were appropriate. Prior to this improvement, virtually all inpatient admissions were subject to potential reversal.
- Unfortunately, like many Medicare policies, the 2-Midnight Rule has become standard policy for most hospital admissions, even for patients who are not Medicare beneficiaries.

Despite CMS' attempts to improve the 2-Midnight Rule, it continues to cause serious problems for the appropriate care of patients who present to the hospital emergency department. The 2-Midnight Rule is based on the premise that acute conditions have a predictable course of treatment and recovery, so that admitting physicians can gauge the length of stay appropriate for each patient who presents in the emergency department. The Rule also assumes that brief observation periods can be utilized to ascertain the need for acute inpatient treatment.

This rationale simply does not apply to the treatment of patients with mental health and substance use disorders, for a number of reasons.

• It is not possible for psychiatrists to predict how long an individual patient with mental health and substance use disorders needs to be in the hospital. This is especially true for patients who present to the emergency department in acute crises, or with serious mental illness, such as schizophrenia. Unlike heart attacks, broken bones, and similar physical or medical issues that bring most patients to the emergency department, mental health issues affect each patient differently, and the course of treatment and recovery is very individual to each patient's condition(s) and circumstances. There is no "typical" recommended length

of stay for a suicide attempt, psychotic break, or opioid overdose, as there is for most physical and medical conditions. What is appropriate for one patient may have catastrophic consequences for another.

- The 2-Midnight Rule is in direct conflict with state laws. All state laws have special rules with respect to the admission (and discharge) of patients with mental health and substance use disorders. These special state laws and policies are in direct conflict with the 2-Midnight Rule. As a result, inpatient admissions, which are in compliance with these state rules, risk being invalidated under the Medicare 2-Midnight Rule. This conflict places psychiatrists and inpatient units in a no-win situation. Given the widespread, serious shortage of inpatient beds for these patients, this in turn raises serious safety and access issues.
 - Patients with serious mental illness who pose a risk of harming themselves or others are <u>required</u> to be admitted to the hospital. State law requires this inpatient hospitalization, even if the patient may only need to be admitted for one night.
 - Patients who present for acute inpatient psychiatric treatment usually present under "involuntary status." State laws allow between <u>72 and 120 hours</u> for proper evaluation and assessment prior to determining continued stay or safely discharging the patient.
 - Patients who present after an attempted overdose or suicide attempt may be eligible for discharge after only <u>one night</u> as an inpatient, if the physician and staff have adequately assessed the situation, and determine it is safe to do so. Yet doing so risks invalidation of that admission as an inpatient stay, under the 2-Midnight Rule.
- The 2-Midnight Rule is causing patients with mental health and substance use disorders to be inappropriately "boarded" in emergency departments, impeding their recovery. Unfortunately, the boarding of patients in hospital emergency departments has become a commonplace and accepted practice, sometimes due to a lack of sufficient psychiatric beds, or due to reimbursement reasons such as the 2-Midnight Rule. While this is not an ideal situation for any patient, this is particularly disadvantageous for patients with mental health or substance use disorders. Emergency departments are often a high stress and chaotic environment. Patients with mental health and substance use disorders need a stable and calming environment, and anything less could prolong their recovery.

What happens when, prior to the second midnight, the patient is evaluated and determined to no longer be a danger? The patient is discharged, and then the beneficiary, the hospital, and the psychiatrist are left to deal with the denied Part A claim and the resulting confusion about the patient's cost-sharing amount. It would be far more appropriate for patients being admitted with a psychiatric diagnosis to be exempted entirely from the 2-Midnight Rule. Psychiatric admissions are a very small portion of all inpatient admissions. But the administrative burden of appealing denied claims is an onerous burden on psychiatrists and the hospitals in which they serve.

II. CMS Should Refine Its Policies to Remove Barriers and Penalties for Appropriate Prescribing of Psychotropic Medications for Patients with Mental Health and Substance Use Disorders

CMS has implemented a number of policies to protect patients from being given medications simply to sedate them, especially patients with dementia who reside in long-term care. The APA fully understands that safeguards are needed to protect these patients from inappropriate prescribing practices that place the convenience of the caregiver above the interests of the patient. However, these policies are having unintended consequences by preventing (or penalizing) psychiatrists who want to prescribe these (or similar) medications to patients who need them. They are also hindering the ability of psychiatrists to place these patients in facilities at the level of care that is most effective for their conditions. Access to facilities is already a problem for many patients with mental health and substance use disorders. This is particularly harmful in states and regions with few options. The APA urges CMS to refine these policies to exempt appropriate prescribing for patients with mental health and substance use disorders.

Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities

CMS set new policies for long-term care (LTC) facilities in the 2016 final rule entitled "Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities." (81 Fed. Reg. 68688, Oct. 4, 2016). The first phase of the final rule became effective November 28, 2016. In the second and third phases, CMS continues to update the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. Considering the high level of treatment variation and gaps in the quality of care that can be found in this type of setting, we appreciate CMS' efforts to ensure patient safety for this population. Furthermore, we support the use of quality measurement to increase positive clinical and patient reported outcomes. However, these new policies, while well meaning, have had unforeseen unintended consequences for psychiatrists and their patients.

We have very serious concerns about the effects on patients with mental health and substance use disorders of this increased scrutiny of prescribing practices for psychotropic medications¹ in LTC care settings. We have heard from a number of APA members working in nursing home facilities and other long-term care settings, throughout the United States who have explained that these new policies, coupled with a lack of standardized guidance for surveyors, have led to improper rejections/citations for <u>appropriate</u> pharmaco-therapeutic decisions and documentation by psychiatrists, and this has become very detrimental to their patients. This also creates a new and significant administrative burden for psychiatrists.

Not only are the revisions to section 483.45 of the Pharmacy Services regulations alarming, and have a discriminatory effect on patients with mental health and substance use disorders, but the minimal standardized guidance provided to CMS surveyors is problematic. The increased oversight of antipsychotic prescribing practices in LTC facilities is not a new initiative for CMS. APA strongly supports the emphasis on ensuring patients, especially those with conditions like dementia, are appropriately prescribed these medications. However, the updated regulations now specify that pharmacies in long-term care settings must initiate monthly drug regimen reviews (DRRs) for patients prescribed psychotropic medications. Psychotropic medications and antibiotics are the only two classes of medications that CMS has specifically targeted for gradual dose reduction or discontinuation, and replacement with behavioral interventions.

This is troublesome for several reasons. When conducting a DRR, pharmacists can review laboratory test results in the patient's record to determine whether a prescribed antibiotic is clinically appropriate. Presumably, this would suffice as adequate documentation. During an onsite review, surveyors can ascertain that a proper DRR was completed, and based on the facility's continuation or discontinuation of the antibiotic, it is easy to illustrate compliance with the rule. However, the final rule does not stipulate what constitutes sufficient documentation to support diagnoses, which are not captured by laboratory tests, such as major depressive disorder, bipolar disorder, and schizophrenia. As a result, there is limited guidance on appropriate documentation to support the prescribing, or continued prescribing, of psychotropic medications. Facilities are being wrongly cited for noncompliance with, or resistance to, a required gradual reduction in the administration of psychotropic

¹ Psychotropic medications include "any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories: (i) Anti-psychotic; (ii) Anti-depressant; (iii) Anti-anxiety; and (iv) Hypnotic." 81 Fed. Reg. 68863.

medications. When patients who were stabilized with appropriately prescribed psychotropic medications are subjected to an inappropriately reduced or discontinued dosage of psychotropic medications, they become unstable, and risk placement in settings with higher levels of care (such as emergency departments and inpatient psychiatric facilities).

Furthermore, after being re-stabilized and discharged from these higher-level care settings, they have difficulty attaining future placement in long term care settings. These patients are liable to experience an overall reduction in their quality of life and may have difficulty communicating their needs or having them addressed, since LTC facilities have fewer professional staff and less patient monitoring than in more acute facilities.

Another determination finalized in this rule that has given APA members cause for concern is the limitation applied to psychotropic PRN (*pro re nata*, or when necessary) prescribing, also found in section 483.45. As finalized, the rule limits the duration of psychotropic PRN orders to no more than 14 days. This is concerning for psychiatrists, including those who work in these facilities, because allowing a psychotropic PRN order often results in less frequent administration, at variable times per week as needed. But due to the 14-day psychotropic PRN limitation, this patient would instead face a higher dose of medications over longer and more frequent periods. As a result of the 14-day psychotropic PRN updates, the final rule states that the use of PRN antipsychotics requires face-to-face reassessments within 14 days of initiation. This timeframe for reassessment is unrealistic, due to current access to care issues for several care settings. We agree that follow-up care is integral to the provision of high quality care. However, CMS continues to allow PRN prescriptions and orders for other, non-psychotropic medications to extend beyond 14 days, and many of those medications carry similar risks for inappropriate prescribing. We invite CMS administrators to work with the APA and other stakeholders to determine alternatives to the PRN limitation on psychotropic medications.

CMS Quality Measure: Percent of Residents Who Newly Received an Antipsychotic Medication

The APA also has major concerns with the current specifications and utilization of the quality measure, "Percent of Residents Who Newly Received an Antipsychotic Medication," for patients in long-term and short-term care. This measure was originally developed to examine the rates of antipsychotic prescriptions for patients in the CMS National Partnership to Improve Dementia Care Program. The goal was to discourage giving antipsychotics to patients with dementia, simply in order to sedate them or decrease their troublesome behavior.² CMS recently announced it was adding the measure to the Nursing Home Compare website's "5-Star Ratings Program." Unfortunately, the widespread, indiscriminate application of this measure to patients with mental health and substance use disorders is impeding and penalizing providers who are appropriately prescribing antipsychotic medications for such patients.

The measure specifically excludes only patients with a diagnosis of: a) schizophrenia; b) Tourette's syndrome; or c) Huntington's Disease. It fails to exclude from its application patients with bipolar disorder or schizoaffective disorder, for whom antipsychotics have proven particularly effective and beneficial. For these patients, there are serious and far-reaching consequences if they are unable to receive the medications they need. Not only does this impact patients' physical and mental health and overall quality of life, but it can impact their ability to reside in long-term care or skilled nursing facilities.

Now with this measure planned for inclusion in the Nursing Home Compare website, it will be used in the calculations that CMS makes for each nursing home listed on the website published "5-Star Rating System." The more prescribing that occurs, the worse the rating. This in essence penalizes psychiatrists and other

² The specifications do not state which types of patients to include in the numerator. However, by virtue of this measure being used in the National Partnership to Improve Dementia Care Program, data reported reflects patients with dementia.

professionals who <u>appropriately prescribe antipsychotics for their patients</u>. The Rating System and Nursing Home Compare were both developed as a tool for consumers to use to make choices regarding their health care. Through considering this measure and the flaws we see within the specifications for patients with bipolar disorder or schizoaffective disorder, we question whether it is achieving its originally intended goal.

This measure was not evaluated (or endorsed) by the National Quality Forum, so there is no information available on its validity, reliability, or feasibility for programmatic implementation. We agree that sufficient evidence exists to measure variation in practice among this care setting and population. But the limitations created by this measure's specifications make us question whether it adequately captures the data needed to assist in the appropriate reduction of antipsychotic prescribing practices in this care setting.

APA staff reached out to CMS officials to learn who the measure developer and steward is, so we could contact them directly to discuss these concerns. However, we were informed that "CMS would not release information on the measure developer and there is no plan to alter the measure specifications." **Thus, we have not had an opportunity to present evidence supporting the inclusion of patients with bipolar disorder or schizoaffective disorder into this quality measure's exclusions.** In other words, this measure should not automatically count prescriptions of antipsychotics written to patients with bipolar disorder or schizoaffective disorder, as an indication of poor quality care. As currently specified, clinicians and facilities providing care for these patients would likely receive a lower rating as under this measure.

CMS typically posts quality measures for public comment prior to their adoption, including details about the measure's specifications, etc. APA has been unable to find any such opportunity or details. Moreover, APA staff has been requesting an opportunity to view the measure specifications since 2013. If this measure has not undergone the open public comment process, then there is a serious lack of transparency in its adoption and utilization, which prevents APA and other stakeholders from advocating for the interests of psychiatrists and the safe treatment of patients.

APA respectfully requests that CMS and the measure's developer or steward review and consider the following evidence. We call upon CMS and the measure's developer or steward to amend the measure specifications to specifically exclude patients with bipolar disorder or schizoaffective disorder.

A review of the literature demonstrates support for the use of antipsychotic medications, either as the main therapy ("monotherapy") or adjunctive treatment, to treat older adults with bipolar disorder or schizoaffective disorder.

Bipolar Disorder. Post-hoc analyses of large randomized controlled trials and small case studies demonstrate the support for the efficacy and safety of antipsychotic medications for older adults with bipolar disorder (OABD). The use of antipsychotics in this population is common, with one cross-sectional study reporting the most frequent medications being taken in the OABD group were the "atypical" antipsychotics (aripiprazole, quetiapine, risperidone, olanzapine, and clozapine) (75.3 percent).³ Similarly high numbers were reported in another study.⁴

³ Rej S, Herrmann N, Shulman K, Fischer HD, Fung K, Gruneir A. Current psychotropic medication prescribing patterns in late-life bipolar disorder. *International Journal of Geriatric Psychiatry*. 2016 Dec 2.

⁴ Oostervink F, Nolen WA, Kok RM, EMBLEM Advisory Board. Two years' outcome of acute mania in bipolar disorder: different effects of age and age of onset. *International Journal of Geriatric Psychiatry*. 2015 Feb;30(2):201–9.

- A prospective study of 22 patients demonstrated that aripiprazole at a dose of 10.3 mg/day was effective as an adjunctive mood-stabilizer with significant improvements of manic and depressive symptoms as assessed by the Young Mania Rating Scale (YMRS) and Hamilton Depression Rating Scale (HAM-D), respectively.⁵
- Another small study involving risperidone at 1-2 mg/day indicated improvement in symptoms of a mixed episode.⁶
- Treatment-resistant patients taking clozapine showed a clinical response to psychotic mania⁷ and remission of symptoms followed by stability in a separate study involving administration of 2.5 milligrams per day of olanzapine.⁸
- In a randomized controlled trial of quetiapine at a dose of 400-800 milligrams per day, a reduction on the YMRS was observed by day 4 versus placebo, and this reduction was sustained through 12 weeks.⁹
- A small study on asenapine monotherapy for acute bipolar mania over 4 weeks found only mild sedation in a fraction of patients, but with 64 percent of subjects achieving remission of symptoms, and 82 percent responding to treatment as measured by the YMRS.¹⁰
- In a post hoc analysis of an older cohort with bipolar depression treated in a randomized controlled trial, lurasidone, approved by the Food and Drug Administration for the treatment of bipolar depression, demonstrated significant antidepressant efficacy at multiple doses compared with placebo as measured by the Montgomery-Asberg Depression Rating Scale (MADRS).¹¹
- Additionally, a recent study in 141 older adults found that long-term treatment with lurasidone led to improvement on the MADRS and low rates of switching to hypomania or mania, yet also related to only minimal changes in weight and median total cholesterol, demonstrating its long-term tolerability.¹²

⁸ Nicolato R, Romano-Silva MA, Correa H, dos Santos RR, Teixeira AL. Stuporous catatonia in an elderly bipolar patient: response to olanzapine. *Australia-New Zealand Journal of Psychiatry*. 2006 May;40(5):498.

⁵ Sajatovic M, Coconcea N, Ignacio RV, Blow FC, Hays RW, Cassidy KA, et al. Aripiprazole therapy in 20 older adults with bipolar disorder: a 12-week, open-label trial. *Journal of Clinical Psychiatry*. 2008 Jan;69(1):41–6.

⁶ Madhusoodanan S, Brenner R, Araujo L, Abaza A. Efficacy of risperidone treatment for psychoses associated with schizophrenia, schizoaffective disorder, bipolar disorder, or senile dementia in 11 geriatric patients: a case series. *Journal of Clinical Psychiatry*. 1995 Nov;56(11):514–8.

⁷ Shulman RW, Singh A, Shulman KI. Treatment of elderly institutionalized bipolar patients with clozapine. *Psychopharmacology Bulletin*. 1997;33(1):113–8.

⁹ Sajatovic M, Calabrese JR, Mullen J. Quetiapine for the treatment of bipolar mania in older adults. *Bipolar Disorder.* 2008 Sep;10(6):662–71.

¹⁰ Baruch Y, Tadger S, Plopski I, Barak Y. Asenapine for elderly bipolar manic patients. *Journal of Affect Disorders*. 2013 Feb 15;145(1):130–2.

¹¹ Sajatovic M, Forester BP, Tsai J, Kroger H, Pikalov A, Cucchiaro J, et al. Efficacy of Lurasidone in Adults Aged 55 Years and Older With Bipolar Depression: Post Hoc Analysis of 2 Double-Blind, Placebo-Controlled Studies. *Journal* of Clinical Psychiatry. 2016 Oct;77(10): 1324–31.

¹² Forester BP, Sajatovic M, Tsai J, Pikalov A, Cucchiaro J, Loebel A. Safety and Effectiveness of Long-Term Treatment with Lurasidone in Older Adults with Bipolar Depression: Post-Hoc Analysis of a 6-Month, Open-Label Study. *American Journal of Geriatric Psychiatry*.

In summary, the classification of the atypical medications as antipsychotics is "misleading" due to their observed efficacy as mood stabilizers for older adults with bipolar disorder.¹³

Schizoaffective Disorder. Although the literature is more limited regarding the use of antipsychotics for treatment of schizoaffective disorder, studies do indicate both the efficacy and the safety of these medications even in 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.¹⁴
- 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.¹⁵
- 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.¹⁶ Among other reasons, one explanation for this change could be due to atypical antipsychotics lacking the Parkinsonian side-effects of the typical antipsychotics, making them a safer option for pharmacotherapy.
- 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.¹⁷

¹³ Vieta E, Günther O, Locklear J, Ekman M, Miltenburger C, Chatterton ML, et al. Effectiveness of psychotropic medications in the maintenance phase of bipolar disorder: a meta-analysis of randomized controlled trials. *International Journal of Neuropsychopharmacology*. 2011 Sep 1;14(8):1029–49.

¹⁴ Glick ID, Mankoski R, Eudicone JM, Marcus RN, Tran Q-V, Assunção-Talbott S. 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*. 2009 May;115(1–2):18–26.

¹⁵ Zisook S, Kasckow JW, Lanouette NM, Golshan S, Fellows I, Vahia I, et al. Augmentation with citalopram for suicidal ideation in middle-aged and older outpatients with schizophrenia and schizoaffective disorder who have subthreshold depressive symptoms: a randomized controlled trial. *Journal of Clinical Psychiatry*. 2010 Jul;71(7):915–22.

¹⁶ Talaslahti T, Alanen H-M, Hakko H, Isohanni M, Häkkinen U, Leinonen E. Change in antipsychotic usage pattern and risk of relapse in older patients with schizophrenia. *International Journal of Geriatric Psychiatry*. 2013 Dec;28(12):1305–11.

¹⁷ Joshi K, Lin J, Lingohr-Smith M, Fu D-J, Muser E. Treatment Patterns and Antipsychotic Medication Adherence Among Commercially Insured Patients With Schizoaffective Disorder in the United States. *Journal of Clinical Psychopharmacology*. 2016 Oct;36(5):429.

In short, it is clear that long-term treatment with antipsychotic medications is an effective and medically appropriate foundation of care for older patients with bipolar disorder and schizoaffective disorder. For these patients, tapering and discontinuation of antipsychotic medications will jeopardize their mental health and their well-being. Older patients with bipolar disorder or schizoaffective disorder in long-term care settings whose psychiatric disorders are being effectively treated with antipsychotic medications may need to receive these indefinitely, for optimum care and effective treatment of their mental health.

The seriousness of this situation is illustrated best by these real-life examples provided days ago by one APA member psychiatrist:

"Unless the ruling does allow an exemption for people with schizophrenia and related diagnoses, schizophrenia must be specifically noted. We have several long-term care facilities that have stopped all antipsychotics even for people with well documented schizophrenia and even with clear psychiatric input and case management support, due to the ruling and fear of a "bad mark" with the subsequent problems noted—admissions (back) to an acute setting and refusal to take the client back. Even worse outcomes have happened, such as a patient too psychotic and paranoid after her antipsychotics were stopped to tell the nurses about pain she was having and subsequently died from lack of attention due to an easily reversible infection. So, it is very, very important to have all the forms of schizophrenia included."¹⁸

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., Associate Director of Payment Policy, at <u>dlansey@psych.org</u> or (202) 609-7123, regarding the 2-Midnight Rule; and Samantha Shugarman, M.S., Deputy Director of Quality, at <u>sshugarman@psych.org</u> or (202) 559-3606, about the policies that affect psychiatrists' prescribing practices.

Sincerely,

Saul Lewin us, men

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

¹⁸ Statement of APA member psychiatrist who is a county medical director for behavioral health and recovery services. He wishes to remain anonymous to protect the identity of his patient.