AMERICAN PSYCHIATRIC ASSOCIATION

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September 14, 2015

Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: [CMS–3260–P] RIN 0938–AR61 Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities

Dear Acting Administrator Slavitt,

On behalf of the American Psychiatric Association (APA), the national medical specialty society representing more than 36,000 physicians specializing in psychiatry, we are submitting these comments in response to the Center for Medicare and Medicaid Services' (CMS) *Proposed Rule for the Reform of Requirements for Long-Term Care Facilities* (the Proposed Rule). APA values the opportunity to comment on the important policy changes that CMS has proposed in this major overhaul of long-term care (LTC) facility regulations, and we thank you in advance for your consideration of these matters.

Nearly one in five older Americans has one or more mental health or substance use disorders (MH/SUD). These conditions are debilitating by themselves and also exacerbate other chronic medical comorbidities. For example, the presence of depressive disorders among the elderly often adversely affects and complicates the treatment of other chronic diseases.[1] Furthermore, older adults with depression visit the doctor and emergency department more often, use more medication, incur higher outpatient charges, and stay longer in the hospital on average.[2] Moreover, nursing facility patients experience high rates of Alzheimer's disease and other forms of major neurocognitive disorders (also known as dementia) that frequently limit their ability to participate fully in care planning due to significant cognitive impairment. Psychiatrists play a critical role in the management of chronic and debilitating psychiatric disorders among nursing facility residents and other elderly individuals in specialty and general treatment settings. We appreciate the opportunity to comment on CMS' proposals.

Reduction of inappropriate use of antipsychotic medications and expansion of antipsychotic-related requirements to all "psychotropics"

While APA shares concerns related to potential overreliance on psychotropic medication use in LTC facilities, we strongly disagree with CMS' approach to addressing this issue. In general, the Proposed Rule's emphasis on adverse side effects obscures the reality that these medicines, when used appropriately, relieve painful and

[1] Chapman DP, Perry GS, Strine TW (2005). The vital link between chronic disease and depressive disorders. Prev Chronic Dis; 2(1):A14.
[2] U.S. Department of Health and Human Services (1999). Older Adults and Mental Health. Mental Health: A Report of the Surgeon General

distressing symptoms and markedly improve quality of life. We hope to serve as a resource to CMS on our shared goals of improving the quality of care available to nursing residents.

APA remains concerned with potential overuse of antipsychotic medication regimens for elderly individuals suffering from Alzheimer's (and other major neurocognitive disorders) when these treatments are not the most appropriate option to meet individual clinical circumstances. We likewise remain concerned with the variety of factors that lead to inappropriate prescribing (e.g., the need to improve primary care clinician training, lack of access to specialty psychiatric physician care for elderly individuals, potential administrative pressure to inappropriately prescribe antipsychotics, and sparse facility staffing requirements that exacerbate this problem). APA maintains relevant evidence-based practice guidelines for the treatment of individuals with Alzheimer's Disease and other major neurocognitive disorders[3] that are available for public viewing. In 2013 APA, as part of the American Board of Internal Medicine's *Choosing Wisely* campaign, recommended that physicians should not routinely use antipsychotics as a first choice to treat behavioral and psychological symptoms of dementia:

> Behavioral and psychological symptoms of dementia are defined as the non-cognitive symptoms and behaviors, including agitation or aggression, anxiety, irritability, depression, apathy and psychosis. Evidence shows that risks (e.g., cerebrovascular effects, mortality, parkinsonism or extrapyramidal signs, sedation, confusion and other cognitive disturbances, and increased body weight) tend to outweigh the potential benefits of antipsychotic medications in this population. Clinicians should generally limit the use of antipsychotic medications to cases where non-pharmacologic measures have failed and the patients' symptoms may create a threat to themselves or others. This item is also included in the American Geriatric Society's list of recommendations for "Choosing Wisely."[4]

APA's practice guidelines recommend a set of core psychiatric management practices designed to treat a patient safely and comprehensively. These practices include:

1) Constructing an alliance between the physician, patient, families, and other care providers;
2) Educating and supporting the patient and family concerning diagnosis, expected symptoms, and basic principles of care;
3) A thorough diagnostic evaluation coordinated with the patient's primary care practitioner; and
4) Regular and comprehensive assessment and monitoring of the patient's psychiatric status and the safety of both the patient and others.

APA strongly supports the use of psychosocial treatments and other non-pharmacological interventions for patients with dementia. Given changes in liver and kidney function that often accompany aging and affect medication pharmacokinetics, pharmacological treatments must be considered carefully by a physician in consultation with the patient and family. When pharmacological treatments are deemed appropriate as a part of a patient's treatment regimen, APA recommends using low starting doses, small dose increases, and long intervals between dose

[3] http://psychiatryonline.org/guidelines
[4] http://www.choosingwisely.org/societies/american-psychiatric-association/

increases. APA explicitly cautions physicians to be alert for medication side effects that may pose particular problems for patients with dementia.

We appreciate CMS' focus on this issue. However, we are troubled by a pervasive theme within the Proposed Rule that frames antipsychotic and other psychotropic medication treatments for elderly individuals (including those with underlying schizophrenia) in a generalized negative light – with new proposed stringent criteria for review and discontinuation without clear evidence that the benefits of discontinuation or limits on use are necessary or best for all patients. This is despite CMS' assertion that "proposed requirements concerning psychotropic medications are not intended to have a chilling effect or in any manner discourage the prescription or use of any medication intended for the benefit of a resident who has been diagnosed for a specific condition that requires these medications". Though this may not be the intent, layer after layer of questioning and justifications for clinical decision-making may result in reducing access to needed care and decreasing clinician morale (with associated workforce implications). Examples of this in the Proposed Rule are numerous (e.g., mandated gradual dose reductions for all psychotropics unless "clinically contraindicated" – a standard without definition in the Proposed Rule).

Practical realities dictate that clinicians will weigh their time invested in caring for patients vs. their time invested in documenting/justifying routine treatment decisions - and make career practice choices per those influences. In summary, APA is concerned that through its proposed significant expansion of psychotropic administration oversight requirements CMS does not adequately appreciate that appropriate, evidence-based psychiatric and pharmacologic therapy for nursing facility residents suffering from MH/SUDs frequently leads to significant quality of life improvement through the associated symptom improvement.

CMS has proposed to revise the current requirements that apply to antipsychotic drugs to apply to any psychotropic drug "that affects brain activities associated with mental process and behavior". CMS further proposes that the definition of "psychotropic drug" be "drugs that affect brain activities associated with mental processes and behavior". While some classes of specific psychopharmaceuticals are listed as examples (e.g., anti-depressants, anxiolytics, and hypnotics), the definition includes catch-all language that covers "any other drug that results in effects similar to the drugs listed above [includes those previously listed and others]". APA interprets this definition as clinically arbitrary and covering almost every medication in the U.S. Pharmacopeia, since large swaths of approved medications affect mental processes and behavior, or have the potential to affect these attributes, due to side effects or interaction with other medications. **Psychiatric medications have been singled out here in a way that simply is not clinically meaningful, and we are very concerned about the proposed broadening of these requirements.**

CMS has also proposed requiring attending physicians to document in the resident's medical record that he or she has reviewed "irregularities" identified by a facility's consultant pharmacist. CMS' examples of irregularities include a drug given for an excessive duration or prescribed without "adequate indications" documented in the resident's medical record. Forcing physicians to document their rationale in instances like these may seem innocuous, but it can become problematic if payers and regulators enforce extremely rigid "appropriate use" criteria, effectively denying care. We understand from APA member experience that patients and families are already seeing the negative effects of such practices. For example, some plans have refused to refill medically indicated antipsychotics, even when patients are stable without side effects. **Again, the presumption here is**

that all psychotropic treatments are questionable until proven otherwise – not to mention the fact that consultant pharmacists who are specifically trained in psychiatric pharmacy or geriatric pharmacy are typically in short supply. CMS states that it is clarifying that facility residents "have the right to receive the services and items included in the plan of care" among its greater review of definitions concerning resident rights related to planning and implementing care. APA hopes that if the plan of care includes specific medications that the patient's rights will supersede the pharmacy review policies outlined in the Proposed Rule and through other federal regulations and payer practices.

We note that APA is particularly supportive of greater training and education of physicians and other providers. Given the shortage of psychiatrists, and particularly geriatric psychiatrists nationwide, it is likely that non-psychiatric physicians and other prescribing professionals write the majority of antipsychotic prescriptions in nursing homes. Widely disseminating important information about these medications and their side effects, as well as appropriate practice guidelines such as those promulgated by the APA, would constitute an important step towards ensuring that antipsychotics are prescribed only when deemed safe and appropriately necessary for a patient's overall well-being.

New proposed requirements related to the provision of information to a resident's receiving provider after transfer

CMS is proposing a variety of new information sharing requirements related to resident transfer to new treating facilities (e.g., acute care hospitals, hospice, or psychiatric facilities). These include specific information consistent with the CMS research and literature review, described on page 42190 of the Proposed Rule.

- APA recommends that CMS explicitly include psychiatric advanced directives along with its reference to "advance directive information". Since a sizeable number of individuals with chronic psychiatric illness will require LTC at some point in their life, the explicit inclusion of psychiatric advance directives in this list would recognize the unique issues and preferences that may be expressed by those with psychiatric disorders.

- Since residents covered under these regulations are likely to have significant history of medical treatment, APA recommends that CMS further specify that the communication of "past medical/surgical history" include, at a minimum, items of current relevance or of importance to current clinical decision-making, in order to ensure that the most relevant information is available to new treating providers.

- APA recommends that CMS explicitly specify that severe adverse effects should be transmitted along with a resident's history of allergies.

Disclosure of information for purposes of QAPI compliance

CMS has proposed to clarify that in order to comply with requirements of the Quality Assurance and Performance Improvement (QAPI) program, facilities may be required to disclose or provide access to certain QAPI information related to reporting, investigations, analysis, prevention of adverse events, and documents related to corrective actions. **We urge CMS to balance QAPI compliance activities with the need to ensure openness during quality related facility meetings, which we understand are afforded certain protections under federal law.** If proceedings from such a meeting are not

privileged and can be used in legal actions, open discussion and problem solving will be negatively affected and the quality improvement process will be harmed.

Proposed amendments related to behavioral health service requirements

As proposed by CMS, the new section 483.40(b)(1) includes a requirement that a "facility must ensure that a resident whose assessment did not reveal or who does not have a diagnosis in a mental or psychosocial adjustment difficulty or a documented history of trauma and/or post-traumatic stress disorder does not display a pattern of decreased social interaction and/or increased withdraw, angry, or depressive behaviors unless the resident's clinical condition demonstrates that development of such a pattern was unavoidable". **This language is confusing and would seem to suggest that, by default, any resident who enters a nursing facility without these specific diagnoses is expected to maintain robust social interaction and positive behavior, and that any indication to the contrary must be grounded in the "unavoidable" effect of a clinical condition and for no other reason**. APA is unclear as to what exactly CMS is requiring of facilities in this proposal and respectfully requests clarification.

Updating MH/SUD-related terminology

APA supports CMS' proposal to replace references to "mental retardation" with references to "intellectual disability" throughout LTC facility regulations. APA was pleased to support Rosa's Law (Public Law 111-256), which removed the terms "mental retardation" and "mentally retarded" from federal health, education, and labor law and replaced these terms with the more appropriate individual-first terms "individual with an intellectual disability" and "intellectual disability", which are based on current DSM-5 nomenclature standards. Ensuring that statutory and regulatory terminology keeps up with current scientific understanding of mental health is an important aspect of combating pervasive stigma in this sphere, and we look forward to working with Congress and the Administration to further these efforts.

New proposed requirements related to mandating nursing facility notification to state mental health authorities of all "significant changes" in residents' condition

As you know, Preadmission Screening and Resident Review (PASRR) is a federal requirement that seeks to ensure that individuals with mental illness are not inappropriately placed in nursing homes for long term care. PASRR requires that all applicants to a Medicaid-certified nursing facility be evaluated for mental illness and/or intellectual disability, that they be offered the most appropriate setting for their needs (e.g., in the community, a nursing facility, or acute care settings) and that they receive the services they need in those settings. APA understands that the requirements of the United States Supreme Court's *Olmstead vs L.C.* decision and CMS' conclusion that "many facilities are unclear as to what this provision [PASRR] requires" and "often [...] overlook the PASRR recommendations during a resident's assessment and the development of their care plan" have led CMS to propose that a nursing facility must notify the state mental health authority or state intellectual disability authority when there has been a "significant change in the resident's physical or mental condition". **This proposed requirement is extraordinarily broad, extremely vague, and likely to lead to significant administrative burden to the detriment of patient care or exacerbation of facility disinterest in admitting patients with psychiatric disorders. Moreover, this undefined and highly vague "significant change" standard is likely to overwhelm state**

mental health agencies with widely disparate notifications. APA opposes this proposal and recommends exploring other PASRR compliance efforts that further its original goal, without creating unduly burdensome and questionably useful notification requirements.

Patients' rights terminology amendments related to self-administering medication

CMS has proposed at §483.10(b)(6) to include the resident's right to self-administer medication if the interdisciplinary team has determined that doing so would be clinically appropriate. While this amendment is clearly well intentioned, we note that medications held by an identified patient for self-administration might also be accessible to other residents. Thus, in shared living facilities, some consideration may need to be given to the safety of others as well as the needs and wishes of the patient.

Patients' rights terminology amendments related to right to receive medical care

CMS has proposed to add a new section to §483.10(b)(7) establishing under the rights of individuals in LTC facilities that "these rights cannot be construed as a right to receive medical care that is not medically necessary or appropriate". APA urges CMS to clarify that determinations of medical necessity are based on the judgment of the patient's treating physician, not the policies of patient's services payer.

New proposed facility responsibilities related to patient contact with government officials

A variety of factors have led to the increase of care for individuals with chronic and severe psychotic illnesses in LTC facilities, most notably the trend of state psychiatric facility closure. In very rare cases, these individuals may make calls to family members, 911, governmental agencies, or others with such a frequency that it is perceived as harassing. CMS has proposed new requirements that a facility may not prevent or discourage a resident from communicating with federal, state, or local officials (e.g., health department employees, surveyors, etc.). CMS further states "residents must have the ability to communicate freely with representatives of these entities when they have concerns about quality of care and quality of life". APA respectfully requests the inclusion of nuance in this requirement so that restrictions could be placed on resident communications under select circumstances with close oversight and scrutiny. In these rare cases, the treatment plan needs to be able to specify that restrictions are indicated and the rationale for the restriction is justified.

In general, the need to meaningfully address the geriatric psychiatric workforce shortage

The treatment needs of the resident population covered by the Proposed Rule greatly benefit from specialized care, yet access to a certified geriatric psychiatrist is challenged by significant workforce shortages. Since 1990, only about 2,500 psychiatrists have received subspecialty certification in geriatric psychiatry. This supply is woefully inadequate to meet the future needs of the nation to provide the highest quality of care for elderly Medicare beneficiaries with chronic mental health conditions. The landmark 2012 Institute of Medicine report titled the "Mental Health and Substance Use Workforce for Older Adults" made a number of recommendations to ameliorate this situation. They are overdue for consideration by Congress and the Administration. These include recommendations on coordinating federal workforce development efforts, scholarship and loan forgiveness promotion, and enhancing data collection. **APA urges CMS' attention to the ongoing**

geriatric psychiatric workforce shortage and hopes to be a resource for future collaboration in this effort.

Economic Impact of the Proposed Rule

We note that the Proposed Rule carries significant projected compliance costs (roughly $700 million in annual burden) that are explained in CMS' included regulatory impact analysis. We have concern that these may significantly underestimate the actual costs and personnel-related time required to implement these regulations as proposed. **APA respectfully requests CMS to publish more detailed data that shows the cost of the proposed changes in each listed regulatory area on a per resident basis as well as a per facility basis (e.g., for small, medium, and large facilities).** Publishing this data will further assist in assessing the cost/benefit analysis of the proposed changes and their impact on resident charges and other methods of facility revenue generation.

Thank you in advance for your review and consideration of these comments. If you have any questions, or if you would like to discuss these matters further, please contact Matthew Sturm, Director of Legislative and Regulatory Policy, at msturm@psych.org or 703-907-7800.

Sincerely,

Saul Levin, M.D., M.P.A.

CEO and Medical Director