

American Psychiatric Association

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February 25, 2014

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Joe Pitts
Chairman
Energy and Commerce Health Subcommittee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Energy and Commerce Health Subcommittee
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

Dear Representatives Upton, Waxman, Pitts and Pallone:

I write on behalf of the American Psychiatric Association (APA), the medical specialty association representing approximately 35,000 psychiatric physicians and their patients and families, to express appreciation for your convening this important hearing on recent proposed rulemaking from the Center for Medicare and Medicaid Services (CMS) regarding the Medicare Part D program. APA is deeply concerned about the proposed rule's potential impact on the well-being of Americans who suffer from mental illness that will be created by limiting Medicare patients' access to medically necessary pharmaceutical treatments.

Currently Medicare Part D beneficiaries have coverage for all or substantially all medications in six protected classes of pharmaceuticals that are prescribed to treat conditions including mental illness, epilepsy, cancer, and HIV/AIDS. Recent proposed rulemaking from CMS would remove antidepressants and antipsychotics from the protected classes, leaving those with severe and persistent mental illness, i.e. the most medically vulnerable elderly and disabled individuals who often suffer from multiple comorbid medical conditions, without medically appropriate treatment options to address their disease.

We are especially troubled that CMS used the criterion that drugs in a category must not be clinically interchangeable (as defined by this proposed rule) to support the elimination of antidepressants and antipsychotics from the protected classes. We find it particularly disturbing that CMS used selective and improper references to APA Treatment Guidelines as justification for limiting coverage of these medications so essential for the treatment of Medicare beneficiaries with mental illnesses



CMS misrepresents APA's relevant practice guidelines. In the proposed rule it provides a quote taken out of context, "the effectiveness of antidepressant medications is generally comparable between classes and within classes of medications," to support its proposed limited coverage for these drugs. The full quote leads to a very different conclusion:

Because the effectiveness of antidepressant medications is generally comparable between classes and within classes of medications, the initial selection of an antidepressant medication will largely be based on the anticipated side effects, the safety or tolerability of these side effects for the individual patient, pharmacological properties of the medication (e.g., half-life, actions on cytochrome P450 enzymes, other drug interactions), and additional factors such as medication response in prior episodes, cost, and patient preference.¹

In other words, the choice among antidepressants should be made on the basis of a variety of important factors including tolerability of side effects, precisely because all antidepressants are not comparable in these respects. The selective quoting from our guidelines and flawed clinical logic apparently led CMS to conflate the supposed "interchangeability" of drugs within the classes of both antidepressants and antipsychotics with overall evidence for efficacy, when this is just one element of a drug's appropriateness for an individual patient.

CMS also cited the APA Treatment Guidelines in support of its claim that there is a "lack of unique effects for distinguishing individual drug products when initiating drug therapy" and that "treatment guidelines ... generally do not advocate a preference of one SSRI drug over another for initiation of therapy." CMS's conclusion is not supported by the evidence it cites. **It misinterprets and misrepresents APA's clinical practice guidelines multiple times as justification for limiting patient access to medically necessary psychotropic medications.**

APA guidelines that address the use of antidepressants and antipsychotics, including the guidelines on major depressive disorder, anxiety disorders, schizophrenia, and obsessive compulsive disorder, all recommend the opposite of CMS's interpretation. They recommend that choice of medication must be made on the basis of how a drug's unique effects may interact with a patient's individual situation. This includes such factors as gender, pregnancy status, age, ethnicity, co-occurring psychiatric conditions, and other co-occurring medical conditions. These unique drug effects include different mechanisms of action, pharmacological properties (e.g., drug-drug interactions), side effects, and safety concerns.

In addition to concerns about drug interactions for patients with comorbid medical and psychiatric conditions, there is tremendous individual variation in patients' ability to tolerate side effects. For example, one antipsychotic class drug may give a patient with schizophrenia parkinsonian side effects like tremors, stiffness, and drooling. A different drug may cause weight gain. Another option could control hallucinations and delusions *without* these side effects for this patient. Given the challenge and importance of medication adherence in patients with psychiatric illnesses, all APA practice guidelines emphasize the importance of considering a patient's individual needs and preferences when choosing an antidepressant or an antipsychotic.

APA strongly recommends that both antidepressants and antipsychotics remain categories of clinical concern on Part D formularies. We are currently preparing our full response to CMS's proposed rule, and will shortly share this with you upon its completion. Thank you again for

¹ *Practice Guideline for the Treatment of Patients with Major Depressive Disorder, Third Edition*, pg17
<http://www.psych.org/practice/clinical-practice-guidelines>

looking into this critically important issue. The leadership and members of APA look forward to working with you to better our patients' access to needed psychiatric services and the most clinically appropriate pharmacological interventions.

Sincerely,

A handwritten signature in black ink on a light gray background. The signature reads "Saul Levin" in a cursive script. The first name "Saul" is written in a larger, more prominent hand, and "Levin" is written in a smaller, more compact hand. There is a small flourish or underline under the "n" in "Levin".

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