March 7, 2014

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4159P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposals for Revising the Part D Classes of Clinical Concern and Revoking Physicians’ Medicare Enrollment
File Code: CMS-4159 P
http://www.regulations.gov/#!documentDetail;D=CMS-2014-0007-0002

Dear Administrator Tavenner,

As members of the physician community, we strongly oppose sections of CMS’s Proposed Rule on the Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs which would eliminate antidepressants, and eventually antipsychotics, from the Medicare Part D Prescription Drug Program’s protected drug classes. A strong clinical rationale exists for continuing to include antidepressants and antipsychotics within Part D’s classes of clinical concern. This rationale parallels the rationale for retaining other drug categories as classes of critical concern, such as anticonvulsants, within Part D’s drug formulary. We also object to CMS’s proposed alterations to existing rules concerning revocation of physicians’ Medicare enrollment.

Proposal to Eliminate Antidepressants and Antipsychotics’ Protected Status

First we must state our disagreement with key arguments that CMS offers in support of its decision to change the protected class policy. CMS referenced its nondiscrimination policy (arising from §1860D-11(e)(2)(D)(i) of the Social Security Act) as the basis for its conclusion in 2006 that “Under the existing circumstances, any formularies that did not have all or substantially all drugs in these categories potentially would have been discriminatory for the Medicare-Medicaid beneficiary population…” We believe that the aforementioned section of the Act is rooted in potential adverse selection problems inherent in any insurance program such as the Medicare Part D Prescription Drug Benefit Program. That is, plans depending on their compensation or premiums, may have incentives to avoid beneficiaries with unfavorable risk profiles. Given the preponderance of high cost beneficiaries such as those with psychiatric diagnoses, complex clinical conditions that require access to a range of medically non-interchangeable medications, the probability of selection gaming by plans is high. In our view
the protected class policy mooted this adverse selection risk and we see no change in circumstances that would meaningfully alter this reality. To reverse course and allow plans access to unrestricted formulary selection and management techniques presents unwarranted adverse selection risk against beneficiaries and runs counter to the purpose of §1860D-11(e)(2)(D)(i) of the Act. We cannot envision any formulary review requirements that could be created to mitigate this for this group of beneficiaries.

Patients who are being treated for mental health disorders meet the first proposed criterion’s burden of proof for inclusion as a drug of clinical concern, that if a medication is not provided “within seven days,” a “typical patient” will require hospitalization, have persistent or significant disability, or die. Many mental illnesses are chronic lifelong conditions with both acute and stable phases characterized by a broad array of symptoms, even among patients who have the same or similar diagnoses. If these mental illnesses go untreated, or are inappropriately treated, a patient’s risk of hospitalization, persistent or significant disability, or death is heightened. Although this is particularly true when a patient needs treatment for acute symptoms like suicidality or psychosis, it is also of concern during his/her ongoing “maintenance” treatment. Clinical evidence from population-based studies clearly indicates that the risk of suicide attempts and completed suicide increases for patients with any psychiatric disorder, and this risk can increase exponentially for patients who suffer from disorders like depression, schizophrenia, and anxiety, who are unable to access the antidepressants or antipsychotics that can control their symptoms.

As for the second criterion, interchangeability: Drugs comprising the antidepressant and antipsychotic classes are not interchangeable. The second criterion for retaining drug classes in the Part D formulary erroneously conflates the concept of the clinical “interchangeability” of both antidepressants and antipsychotics with clinical evidence of these drug categories’ efficacy for some percentage of patients. Given the heterogeneity of the mental health disorders that cause psychiatric disability, the universe of potential drug and disease-specific scenarios is far too vast and varied for CMS to capture with specific, limited formulary requirements.

CMS seeks to justify its proposal to eliminate antidepressants and antipsychotics from Part D’s classes of clinical concern by arbitrarily referencing select lines of a physician specialty’s clinical practice guidelines. We are not aware of any physician treatment guidelines that, when read in context, would advocate for diminishing or limiting patients’ access to antidepressants and antipsychotics, if they suffer from mental health disorders for which these drugs are necessary to treat the conditions or disease. CMS’s selective quoting of physician clinical practice guidelines to justify its proposed elimination of the antidepressant and antipsychotics’ from Part D’s protected classes of clinical concern fails to heed strong recommendations within physician clinical practice guidelines that a drug’s efficacy is only one of many factors, including, but not limited to, a patient’s gender, pregnancy status, age, ethnicity, co-occurring psychiatric conditions, and co-occurring other medical conditions, that physicians must consider when choosing the appropriate medication to prescribe for an individual patient.
CMS’s conclusion that the economic costs of the Medicare D program will be lowered by removing antidepressants, and eventually antipsychotics, from Part D’s protected classes is short-sighted. The potential savings CMS could realize from removing the protected status of antidepressants and antipsychotics would be dwarfed by the increased costs in other areas of the Medicare program and for society in general that are created by the clinical harms that will result from delaying, limiting, or denying vulnerable patients’ access to these medications. CMS’s assertions that this proposal will save money strike us as highly disingenuous since its economic impact analysis fails to account for any of the externality costs likely to result from eliminating antidepressants and antipsychotics’ protected status. A 2011 study by the American Psychiatric Institute for Research and Education found that Medicaid patients receiving Medicare prescription drug benefits who were previously stable on their medications but had to switch medications because clinically indicated refills were not covered or approved experienced significantly higher adverse events (62% versus 37%), including emergency department visits, hospitalizations, homelessness, and incarceration.\(^1\)

We further question CMS’s claims that the beneficiary protections afforded by the Part D appeals process can effectively provide Medicare beneficiaries with access to necessary antidepressants and antipsychotics. Even physicians who regularly accept Medicare patients and have familiarized themselves with the Part D appeals process frequently report difficulty in getting their patients access to drugs. We must point out the additional challenges a Medicare beneficiary suffering from a chronic mental illness would encounter trying to obtain his/her drugs through the Part D appeals process. We concur with MEDPAC’s findings that the current Part D appeals process is often challenged to provide Medicare beneficiaries with timely access to the prescription drugs that are clinically appropriate for them. We frequently hear from physicians with a patient who tried to file an appeal, but since the intended appeal was categorized as a “complaint” rather than an “appeal,” the patient was not afforded the protections of the appeals process, including adherence to the defined timeline for having an appeal resolved. We find CMS’s arguments in favor of using the Part D appeals process to access clinically appropriate drugs to be unsubstantiated. We also ask what happens in the event that an appeal is successfully submitted, but the patient is denied access to the drug.

We share CMS’s concern about inappropriate use of antipsychotics. However, we don’t want incidents of inappropriate use of antipsychotics to obscure the legitimate needs of many patients suffering from mental health disorders for access to a range of drugs, including antipsychotics. We do not believe that this current proposal to limit the antipsychotics available to Medicare patients is an effective way to reform inappropriate prescribing patterns.

Finally, we question the composition of the consensus panel that devised this recommendation to eliminate the antidepressant class, and eventually the antipsychotics class, from the Part D formulary’s classes of clinical concern. This panel was made up of CMS pharmacists and the Chief Medical Officer for the Center for Medicare. We believe the composition of this panel was not representative of the clinicians responsible for medical care for these patients. We strongly recommend that all future Part D Prescription Drug Benefit Program review panels include physicians from the private sector.

For all of the foregoing reasons, we strongly oppose this Proposed Rule’s plan to eliminate antidepressants, and in 2015, antipsychotics, from Part D’s classes of clinical concern. The inclusion of these two classes in the protected formulary has been a bedrock of the Part D Prescription Drug Benefit Program, and we have advocated for these classes to have protected status since the Part D Program’s inception. We urge CMS not to revise the classes of clinical concern within the Part D formulary. Doing so is not in the best interest of Medicare beneficiaries or of the Medicare program as a whole.

**Revocation of Medicare Enrollment**

CMS proposes alterations to existing rules that would permit it to revoke the enrollment of physicians and other eligible professionals for a number of newly articulated reasons. While we concur with efforts by CMS to revoke the enrollment of individuals who prescribe without the appropriate licensure or a Drug Enforcement Agency (DEA) certificate, the agency exceeds its statutory authority by defining prescribing that is “abusive” and represents a threat to the health and safety of Medicare beneficiaries or otherwise fails to meet Medicare requirements as a basis for revocation of enrollment. We strongly oppose CMS’s attempt to directly regulate the practice of medicine, establish black box clinical practice guidelines, and pre-empt the authority of states to provide oversight over physician (and other licensed health professionals) medical practice. We urge CMS instead to refer prescribers who “fall outside the norm of appropriate prescribing,” based on agency analytics and benchmarking, to the appropriate state licensing board. These bodies are specifically set up and qualified to make such assessments and issue determinations that can be relied upon by CMS as a basis for revoking enrollment, if appropriate.

First, CMS proposes to deny or revoke a physician’s Medicare enrollment if the physician’s DEA certificate is suspended or revoked or if the applicable state licensing or administrative body has suspended or revoked the physician’s ability to prescribe. It is rational, reasonable, and consistent with the agency’s general grant of authority to administer the Medicare program to provide that prescribers lacking appropriate licensure or subject to licensure suspension should be barred from participation in the Medicare program. However, to the extent CMS finalizes the proposal to revoke or deny enrollment based on a licensure or DEA certificate suspension, we ask CMS to remove barriers to re-enrollment in a timely manner once such suspensions are lifted and also to make specific provision to ensure for such an occurrence.
We question whether the denial or revocation of a prescriber’s DEA certificate should preclude the prescriber from legally prescribing non-Controlled Substances even where the prescriber maintains legal authority to do so and is in good standing with a state professional licensing body. CMS does not provide any documented evidence that physicians who have had their DEA certificates terminated or previously suspended are demonstrated to have prescribing practices that are outside the norm across the spectrum of all therapeutic options. We request CMS to evaluate more fully the basis for DEA terminations and suspensions and to determine whether such physicians have demonstrated the same pattern and practice of problems in prescribing medications that are not Controlled Substances. If a physician decides not to seek a DEA certificate after revocation or withdraws registration voluntarily, the physician would remain barred from Medicare enrollment for the remainder of his/her professional career under this Proposed Rule even if the physician otherwise maintained good professional standing. Since CMS has increased program integrity controls to prevent dispensing Controlled Substances written by a prescriber without an appropriate DEA certificate, this permanent bar from the Medicare program seems excessive and unreasonable. We urge CMS to revise the proposed regulation consistent with the above comments.

Second, CMS proposes to establish authority to revoke a physician’s Medicare enrollment if the agency determines that the physician has a pattern or practice of prescribing Part D drugs that: a) is abusive and represents a threat to the health and safety of Medicare beneficiaries; or, b) fails to meet Medicare requirements. The Proposed Rule lists criteria that it would use to make this determination. A number of the criteria identified by CMS are beyond the expertise of CMS regulators to evaluate and would represent an unprecedented move by a federal agency to regulate the practice of medicine directly and supplant the role of state licensing boards, which are specifically created to evaluate the very criteria governing professional conduct CMS now proposes to undertake.

We urge CMS to use the proposed criteria and collect information consistent therewith, including information provided by the Part D plan as well as from the Medicare Drug Integrity Contractor, to submit a comprehensive referral to the relevant licensing board for action, including suspension or termination of licensure, as appropriate for physicians engaged in what the agency concludes would be a threat to the health and safety of Medicare beneficiaries. We ask CMS to strike references to abusive prescribing because the standard has not been defined, is potentially highly subjective, and over time may be inconsistent with community and clinical standards of care as defined by the medical profession. Furthermore, the discretion it would confer on the agency is not consistent with the statutory authority cited by the agency for this section of the proposed rulemaking.
Sincerely,

American Psychiatric Association
American Medical Association
American Academy of Neurology
American Academy of Child and Adolescent Psychiatry
American Association for Geriatric Psychiatry
The Society for Post-Acute and Long-Term Care Medicine
California Psychiatric Association
New York State Psychiatric Association
California Medical Association
Florida Psychiatric Society
Kentucky Psychiatric Medical Association
Arkansas Psychiatric Society
North Carolina Psychiatric Association
Washington State Psychiatric Association
New Jersey Psychiatric Association
Pennsylvania Psychiatric Society
Psychiatric Society of Delaware
Ohio Psychiatric Physicians Association
Arizona Psychiatric Society
Washington Psychiatric Association
South Carolina Psychiatric Association
Louisiana Psychiatric Medical Association
Iowa Psychiatric Society
Maine Association of Psychiatric Physicians
Massachusetts Psychiatric Society
Missouri Psychiatric Association
Maryland Psychiatric Society
Michigan Psychiatric Society
Georgia Psychiatric Physicians Association
Minnesota Psychiatric Society