March 7, 2014 **Submitted via: www.regulations.org**

The Honorable Marilyn B. Tavenner, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: NPRM File Code CMS-4159-P
Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

Dear Administrator Tavenner:

Thank you for the opportunity to comment on the Notice of Proposed Rule Making (NPRM) regarding Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs. The Disability Rights Education and Defense Fund (DREDF) is a leading national law and policy center that advances the civil and human rights of people with disabilities through legal advocacy, training, education, and public policy and legislative development. We are a cross-disability organization, and submit these comments to support a number of aspects in the NPRM. At the same time, we express deep concerns over the NPRM's findings with respect to three of the six protected Part D drug classes and its proposal to modify the protective standards that currently apply to antipsychotics, antidepressants, and immunosuppressants.

General Support for Many Components of NPRM

DREDF strongly supports many aspects of the NPRM's regulatory changes and does not believe that a move to greater regulation of the industry will threaten the overall integrity of the Part D program. In particular, we agree with measures to improve beneficiary notices, raise Medicare plan standards for issuing Part D denials, ensure meaningful differences between Part D plans, increase standardized reporting on negotiated prices, and help to establish fair and accurate preferred pharmacy cost sharing and greater access to preferred pharmacies. We believe that the greater plan oversight and accountability contemplated in the NPRM will improve beneficiary access to affordable prescriptions drugs and treatments and enhance the operation of the Part D program. DREDF also supports the more detailed comments, concerns, and recommendations submitted by National Senior Citizens Law Center (NSCLC) on these specific aspects of the NPRM.

Recommendation Against Proposal to Revise Categories or Classes of Clinical Concern and Exceptions (§ 423.120(b)(2)(v) and (vi))

DREDF is greatly concerned with the NPRM's proposal to loosen protections for the Part D protected classes of antipsychotics, antidepressants, and immunosuppressants. To begin with, we take issue with the findings made by the consensus panel of CMS pharmacists and the Chief Medical Officer for the Center for Medicare convened by CMS. The panel concluded that antipsychotics "are considered to be generally therapeutically interchangeable when initiating therapy, and based on treatment guidelines, our formulary requirements could efficiently ensure appropriate access to antipsychotics without requiring inclusion on the formulary of every drug in the class." We question whether sufficient expertise in mental health disabilities and treatment was included in the panel. DREDF's understanding is that antipsychotics and antidepressants are *not* interchangeable in terms of their often very significant side effects, and this is particularly true for individuals with multiple chronic conditions that include mental and physical disabilities who are subject to treatment interactions that may lack clinical information or research. The side-effects of antipsychotics, both conventional and atypical/second generation, is well-documented,[1] and cited by mental health advocates as a key reason for making the preferences and needs of individual consumers central in the prescription process.

Limiting the protected availability of the full range of antipsychotic and antidepressants in 2015 will make it more difficult for beneficiaries to maintain drug regimens that optimize their overall health and functional capacity to live well and safely in their communities. Limiting the availability of these essential drugs is particularly risky coming at a time when literally hundreds of thousands of Medicare beneficiaries across the country are being required to transition over the next few years to "integrated" managed care delivery of healthcare that, in and of itself, may disrupt existing provider relationships and treatment regimens in both the short and long-term. A new or interim provider, unfamiliar with a beneficiary's history of side-effects and medically complex drug interactions, will not necessarily, willingly, or quickly take the steps needed to support an individual consumer's need for a particular drug that is no longer in a protected category of drugs. Moreover, the Part D appeal system, with its documented shortcomings, is not a reliable or plausible solution to the removal of needed protections for antipsychotics and antidepressants.

Limited Utilization Management of Antipsychotics in Nursing Facilities

Given our fundamental objection to the NPRM's proposal to remove protected categorical status from antipsychotics and antidepressants, DREDF does acknowledge CMS's concern with the abuse of antipsychotics among nursing facility residents, and particularly the medically inappropriate use of antipsychotics with beneficiaries

[1] *See* for example John Wilkaitis, *et al.*, *Chapter 27: Classic Antipsychotic Medications*, *in* The American Psychiatric Publishing Textbook of Psychopharmacology 425, 437 (Alan F. Schatzberg & Charles B. Nemeroff, eds., 3rd ed., 2004); Arshia A. Shirzadi & S. Nassir Ghaemi, *Side Effects of Atypical Antipsychotics: Extrapyramidal Symptoms and the Metabolic Syndrome*, 14 Harv. Rev. Psychiatry 152, 157 (2006); Michael J. Sernyak, *et al.*, *Association of Diabetes Mellitus with Use of Atypical Neuroleptics in the Treatment of Schizophrenia*, 159 Am. J. Psychiatry 561, 561, 565 (2002); Elizabeth A. Koller et al., *Pancreatitis associated with atypical antipsychotics: From the Food and Drug administration's MedWatch surveillance system and published reports*, 23(9) Pharmacotherapy1123 (2003).

diagnosed with dementia. We share this concern and cite as additional support the recent report of the California Advocates of Nursing Home Reform[2] which summarizes an investigation undertaken by the California Department of Public Health.

> [T]he Department of Public Health ("DPH") launched an Antipsychotic Drug Collaborative to inspect selected facilities with potential drugging problems. The results have been stunning, finding 147 violations in 24 facilities, an average of 6.1 deficiencies per facility.
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> The extent of the violations found by the Collaborative is extremely troubling. Forty-one different regulatory rules were violated, ranging from failure to ensure residents have physicians to deficient patient records. Most violations, however, fell within three categories:
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> • Failure to obtain informed consent from residents or their responsible parties for drugs;
> • Use of unnecessary drugs or drugs in excessive dosage; and
> • Deficient pharmaceutical consultant services.[3]

DREDF appreciates the extent of this problem and calls for the development of additional practices to address the abuse of nursing home and institutional residents through chemical restraints. We are not, however, entirely convinced that antipsychotics must be removed as a Part D protected drug class to achieve the goal of ending the abuse. The widespread abuse of antipsychotics in institutional settings violates *existing* regulations, especially as antipsychotic drugs already have an FDA-mandated Black Box warning label that advises nursing home personnel and the public that the drug virtually doubles the risk of death when administered to individuals diagnosed with dementia.[4] We support additional monitoring and enforcement of existing regulations that already apply to the use of antipsychotics, as well as the development and introduction of additional tailored utilization management techniques and controls pertaining to the use of antipsychotics in nursing facilities and institutional setting.

Conclusion

While DREDF supports many of the regulatory proposals made in the NPRM that would lead to additional consumer protections and enhancement of the goals of the Part D program, we ask CMS to not undertake altering the standards for determining protected classes of drugs in the Part D program so that antipsychotics, antidepressants and

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[2] California Advocates for Nursing Home Reform (CANHR), *In a Stupor: What California's Antipsychoticic Drug Collaborative Reveals About Illegal Nursing Home Drugging* (2012), available at http://www.canhr.org/reports/In_a_Stupor.pdf.
[3] *Id.*
[4] U.S. Food & Drug Admin. Public Health Advisory, *Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances* (2005), http://www.fda.gov/cder/drug/advisory/antipsychotics.htm.

immunosuppressants would no longer meet the requirement for enhanced protections. The proposal does not take sufficient account of the complex medical situation and needs of many people with disabilities, including people with mental health disabilities and multiple chronic conditions. Use of the complicated Medicare appeals system will not sufficiently safeguard the needs of individual beneficiaries who will lose needed full access to specific drugs and treatments upon implementation of the proposal.

Thank you again for the opportunity to comment on these regulatory proposals. We would be happy to answer any questions or concerns that you have the above comments.

Yours Truly,

Silvia Yee
Senior Staff Attorney