



VIA ELECTRONIC FILING TO: <http://www.regulations.gov>

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4159-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

Re: Comments on Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs [CMS-4159-P]

Dear Ms. Tavenner:

MAPRx brings together more than 55 patient, beneficiary, family caregiver and health professional organizations committed to improving access to prescription medications and safeguarding the well-being of beneficiaries with chronic diseases and disabilities under the Medicare prescription drug benefit (Part D). For nearly ten years, MAPRx has advocated on behalf of millions of Medicare beneficiaries with chronic conditions who rely on Part D for essential, lifesaving medications. MAPRx submits the following comments in response to the proposed rule regarding Contract Year (CY) 2015 Policy and Technical Changes to the Medicare Advantage (MA) and the Medicare Prescription Drug Benefit (Part D) Programs, published in the January 10, 2014, *Federal Register*.

Specifically, our comments address the following issues raised in the proposed rule:

- Drug Categories or Classes of Clinical Concern and Exceptions (the six protected classes)
- Medication Therapy Management Program under Part D

Drug Categories or Classes of Clinical Concern and Exceptions

Description of the Issue: CMS proposes to interpret several of the statutory terms in section 3307 of the Affordable Care Act (ACA) to better define the scope of the protections of the classes of clinical concern. More specifically, CMS seeks to redefine the clinical classes of concern criteria to only identify those drug categories or classes for which access cannot be adequately ensured by beneficiary protections that otherwise apply. CMS proposes to establish a two-prong test to identify drug classes of clinical concern that will read:

- (1) A typical beneficiary, who is initiating therapy must administer a drug within the category or class in less than 7 days or failure to do so will lead to hospitalization, incapacity, disability or death; and

- (2) Other CMS formulary requirements are not sufficient to ensure the access to an appropriate range of therapies, either due to the diversity of disease or condition manifestations or the associated specificity or variability of drug therapies necessary to treat such manifestations.

Applying this new two-prong test to the universe of Part D drugs, CMS identified three categories or classes of drugs for which unrestricted access remains appropriate: antiretrovirals, antineoplastics, and anticonvulsants. Conversely, application of the new criteria would result in the elimination of the antidepressant and immunosuppressant drug classes from the list of classes of clinical concern effective January 1, 2015. CMS also proposes removing the antipsychotic drug class from the list of protected classes, but will defer any change to Plan Year 2016 as the agency continues to evaluate the need for additional considerations regarding transitions for individuals already taking these medications.

Comments: MAPRx firmly disagrees with the proposed changes to the protected class policy. A number of alarming and potentially destructive beneficiary access issues could arise, if the proposed changes are finalized. Protecting beneficiary access to the most appropriate therapies is critical for those taking medications offered under the protected classes. The protected class policy continues to effectively serve CMS' original intent of providing access to needed medications, and also mitigating complications associated with an interruption of care for vulnerable Medicare beneficiaries.

The vital beneficiary protection offered by the protected class policy provides stability for beneficiaries with serious, chronic medical conditions and often protects those with more than one condition. MAPRx strongly disagrees with CMS' application of the protected class policy to "typical individuals" as adequate justification for the proposed changes. This narrow application of the term ignores the fact that Medicare beneficiaries taking medications under the protected classes are anything but "typical individuals." They are beneficiaries often living with multiple, complex chronic conditions, significant disabilities, and complicated comorbidities. The complexity of both physical and mental care required for these beneficiaries is inappropriately ignored by CMS in their proposal to remove antidepressants, immunosuppressants, and potentially antipsychotics from the list of protected classes.

If finalized, the proposed protected class policy changes would be detrimental for beneficiaries who rely on antidepressants and immunosuppressants (and antipsychotics in 2016). MAPRx fully anticipates Part D plan coverage of these classes to be significantly less generous in 2015 and beyond. In addition, the standard Part D formulary review process would not adequately ensure beneficiary access to antidepressants and antipsychotics. CMS presented data in its proposed rule showing that the combined number of antidepressants and antipsychotics available to patients would be reduced to 15 total drugs and would not require formulary inclusion of any brand name drugs, even those without generic equivalents. By comparison, the current policy guarantees beneficiary access to 57 drugs, including 41 single-source brands. Given that the effectiveness of antidepressant and antipsychotic therapies vary by patient, and can have significant side effects, a wide range of available treatments in each of these classes is imperative to ensure optimal care for patients with debilitating mental disorders. Furthermore, the proposed protected class policy changes are based on a flawed set of assumptions about current beneficiary protections available under the Part D program. For example, CMS states in its proposed rule that beneficiaries can rely on a "robust coverage determination and appeals process." If the proposed change

occurs, beneficiaries may be on medications that are no longer on their plan's formulary. Under this scenario, patients would be charged for the full cost of the medication. If beneficiaries cannot afford this cost, which many cannot, they would postpone treatment until they are able to obtain a formulary exception from their Part D plan. This time lag would be detrimental to the beneficiary. Despite evidence suggesting the contrary, CMS accepts that the existing exceptions, appeals, and grievance processes will sufficiently enable timely access to necessary medication when access is restricted by formulary.

MAPRx rejects the assumption that the Part D appeals processes are a sufficient safeguard for already vulnerable beneficiaries. A recent report by the Medicare Rights Center outlined a number of flaws with Part D appeals, including: 1) many beneficiaries experience a refusal of coverage at the pharmacy counter without an explanation; 2) beneficiaries are unaware of their right to appeal; and 3) lack of transparency and data.

CMS' own recent audits demonstrate consistent failure by Part D plans to efficiently adjudicate the appeals and grievances processes. Additionally, a recent Medicare Payment Advisory Commission (MedPAC) analysis found that most beneficiaries are unaware of how the exceptions and appeals process works¹, further reinforcing our concern that current appeals processes cannot be relied on to ensure beneficiary access to previously protected classes.

If finalized, the proposed change to the protected class policy will increase the frequency of appeals and throw beneficiaries into navigating an unfamiliar, arduous and broken appeals process. Thus, MAPRx would like to take this opportunity to call on CMS to improve the Part D appeals. As initial steps, MAPRx encourages CMS to 1) increase transparency regarding the operational efficiency of the appeals system, which will then enable proper scrutiny of the current process and 2) provide beneficiaries with a timely, written notice of refusal of coverage

Finally, MAPRx rejects CMS' justification for the proposed protected class policy change. In the proposed rule, the Agency cited rising program costs and beneficiary protection concerns as the primary rationale for altering the policy. The Agency further rationalized that existing beneficiary protections are sufficient for ensuring access to drug therapies. As previously noted, since implementation of the Part D benefit in 2006, the protected class policy has successfully ensured beneficiary access to critical drugs within the six protected classes. Further, in a February 5, 2014 letter to CMS, the Senate Finance Committee (SFC) expressed concerns that the proposed changes would "diminish access to needed medication", and "remain unconvinced significant cost savings will be achieved." MAPRx does not recognize potential cost savings alone as an adequate rationalization for finalizing the proposed changes to this historically effective policy.

CMS must fully consider the unintended consequences of removing the protected status for antidepressant, immunosuppressant, and antipsychotic classes. Eliminating protected status for these three classes of drugs will result in an increase in beneficiary out-of-pocket costs and overall costs to the Medicare program if beneficiaries require more frequent physician visits or are hospitalized. A November 2012 Congressional Budget Office (CBO) report acknowledged that increased access to prescription drugs decreases spending for medical services, such as hospital admissions.² Thus, MAPRx suggests that changes to the protected class policy could have a significant ripple effect

¹ Medicare Payment Advisory Commission (MedPAC). "Part D exceptions and appeals." September 12, 2013.

² Congressional Budget Office (CBO). "Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services." November 29, 2012.

on out-of-pocket costs for beneficiaries and additional costs within the Medicare system under Parts A and B.

CMS must withdraw its proposal to alter the protected class policy and preserve beneficiary access to the antidepressants, immunosuppressants, and antipsychotics drug classes.

Medication Therapy Management Program under Part D

Description of the Issue: CMS proposes several potential changes to the Medication Therapy Management (MTM) requirements, including expansion of the eligibility criteria to increase the number of Part D enrollees eligible for MTM. Specifically, the proposed eligibility criteria would include beneficiaries who: have two or more chronic diseases; are taking two or more covered Part D drugs; and, incur at least \$620 in annual Part D drug costs (down from \$3,144). The proposal would also standardize the types and methods of interventions delivered through MTM programs. Based on these proposed changes, CMS estimates approximately 18 million (up from 2.5 million) beneficiaries, or 55 percent of all Part D beneficiaries, will have access to MTM services.

Comments: MAPRx supports CMS' efforts to increase beneficiary access to MTM services. MTM programs often provide beneficiaries with the necessary channels to improve care management for their chronic diseases and conditions. CMS' proposal to target those beneficiaries who have two or more chronic conditions is very helpful to those beneficiaries struggling to manage their diseases.

Additionally, by lowering the annual Part D drug cost threshold from \$3,144 to \$620, and revising the minimum qualifying threshold for MTM services from eight to two Part D drugs, the proposed policy will help ensure plans are targeting a much broader subset of the Part D population for MTM services. MAPRx encourages CMS to finalize the revised MTM eligibility criteria as proposed but urges CMS to continuously monitor the impact of MTM programs on the most vulnerable Medicare populations, such as Low-Income Subsidy (LIS) beneficiaries.

MAPRx urges CMS to consider our comments on the CY 2015 MA and Part D proposed rule. Thank you for your attention to our views. For questions related to MAPRx or the above comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 429-4017 or bonnie@maprxinfo.org.

Sincerely,

Alpha-1 Association

Alpha-1 Foundation

American Association on Health and Disability

American Autoimmune Related Diseases Association

American Cancer Society Cancer Action Network, Inc.

American Society of Consultant Pharmacists

Arthritis Foundation

Asthma and Allergy Foundation of America

COPD Foundation
Epilepsy Foundation
GIST Cancer Awareness Foundation
Hemophilia Federation of America
Lupus Foundation of America
Men's Health Network
Mental Health America
National Alliance on Mental Illness
National Council on Aging
National Kidney Foundation
National Organization for Rare Disorders
Parkinson's Action Network
Patient Services, Inc.
Society for Women's Health Research
Spina Bifida Association
The AIDS Institute
The Arc
The International Foundation for Autoimmune Arthritis
The Leukemia & Lymphoma Society
The National Council for Behavioral Health
United Spinal Association