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Delivered by hand courier

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4159-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Also submitted electronically via <http://www.regulations.gov>

Re: Comments on the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4159-P)

The Partnership for Part D Access (the Partnership) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule titled, "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (the Proposed Rule).¹

The Partnership is a coalition of healthcare stakeholders committed to maintaining access to medications under Medicare Part D, especially the categories and classes of drugs identified for unique patient protections at section 1860D-4(b)(3)(G)(iv) (the "protected classes"). These medications are vital to the treatment of: (1) epilepsy; (2) mental illness; (3) cancer; (4) HIV-AIDS; and (5) organ transplants. The Partnership was founded to combat efforts to undermine consumer access to appropriate treatment by increasing policymaker awareness of the vulnerability of patients with these conditions and the potential impact of delayed or denied care. The Partnership's membership currently includes a variety of patient advocacy organizations, such as the National Council for Behavioral Health (National Council), the National Alliance on Mental Illness (NAMI), Mental Health America (MHA), the Depression and Bipolar Support Alliance (DBSA), The AIDS Institute, the Epilepsy Foundation and the National Kidney Foundation (NKF), as well as industry representatives.

In these comments we identify deep flaws in CMS' approach to implementing section 3307 of the Patient Protection and Affordable Care Act (ACA) (section 3307), which lead us to **respectfully recommend that this entire portion of the Proposed Rule be rescinded.**

In the Proposed Rule, CMS fundamentally misinterprets section 3307 of the ACA by weakening the protected classes policy and transforming a legislative directive to identify classes of *clinical* concern into one targeting classes of alleged *cost* concern. The studies cited by the agency do not support its own cost savings assumptions and the rule ignores the substantial spending associated with the destabilization

¹ 79 Fed. Reg. 1918, Jan. 10, 2014.

of patient care that it will precipitate. Furthermore, the agency inexplicably and falsely assumes that the patient safeguards embedded in the protected classes policy are no longer necessary, promulgates ambiguous new standards that have no basis in clinical evidence, and cites fallback protections whose unreliability has been thoroughly documented by authoritative government sources.

In brief, by using it as a tool for cutting costs at the expense of the most vulnerable Medicare beneficiaries, CMS has directly contradicted Congress's intent to improve and expand the protected classes policy. CMS must revoke this portion of the Proposed Rule and start again with an approach that, at a minimum, guarantees the same degree of patient protection that existed prior to its publication.

I. The Proposed Rule Contradicts Congress's Intent to Protect Patients by Strengthening the Classes of Clinical Concern

A. Legislative History Demonstrates Congressional Intent to Maintain Existing Classes

1. Initial Adoption of Protected Classes Demonstrates Rationale for the Policy

CMS crafted the protected class policy as a component of implementing the non-discrimination provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Those provisions require CMS to reject plans whose design and benefit structure (including formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals.² CMS explained that it "instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in Part D plans and to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."³ CMS reiterated this rationale in the Proposed Rule itself.⁴ Consistent with that rationale, CMS policy protected access to: anticonvulsants (for epilepsy); antidepressants; antineoplastics to treat cancer; antipsychotics; antiretrovirals for HIV/AIDS; and immunosuppressants to prevent rejection of transplanted organs.⁵

When Congress established the Medicare Part D prescription drug benefit, it recognized that certain drug classes were vital to the beneficiaries whose lives, in many cases, depended on those drugs, and that their prescribers needed access to the full range of treatment options. For example, Congress expressed significant concern regarding the needs of Medicare beneficiaries with mental illness, as illustrated in the Conference Report that accompanied the MMA.⁶ According to the Conference Report, CMS would be required to "ensure that Medicare beneficiaries have clinically appropriate access to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression [and other conditions]."⁷

Like the Conference Report, a Senate colloquy that took place just before the MMA's enactment emphasized that Part D would ensure broad coverage of medications to treat illnesses where access to the full array of therapeutic options is necessary to ensure patient safety.⁸ The colloquy pointed to the role of

² 79 Fed. Reg. at 1937.

³ Prescription Drug Benefit Manual, Ch. 6 § 30.2.5.

⁴ 79 Fed. Reg. at 1937.

⁵ Ibid.

⁶ U.S. House of Representatives. Report 108-391, *Medicare Prescription Drug Improvement and Modernization Act of 2003 (to accompany H.R. 1)*. (H.R. Rep. 108-391). Washington: Government Printing Office, 2003 at pp. 769-770.

⁷ H.R. Rep. 108-391 at 770.

⁸ 149 Cong. Rec. S5882-03.

Part D’s non-discrimination provision in protecting beneficiaries with these types of illnesses. The exchange between these senators repeatedly emphasized the many layers of patient protections Congress had purposely built into Part D, including the fundamental protections available to beneficiaries “who need exactly the right medicine for them”:

Mr. BAUCUS.

. . . . One of the things I am particularly proud about in this bill is the strong beneficiary protections You know, Senator Grassley, that there are certain diseases and conditions – like AIDS, and epilepsy – where having access to just the right medicine is especially important.

Mr. GRASSLEY.

I did know that, and I know that certain mental illnesses also fall in that category. This bill contains a number of protections for people who need exactly the right medicine for them. . . .

Mr. BAUCUS.

Exactly. . . . [W]e require drug plans to offer at least two drugs in each therapeutic class. And for drugs that treat AIDS, epilepsy, or mental illness, we would expect that plans would carry all clinically appropriate drugs.

Mr. GRASSLEY.

I agree. And I am pleased with the backup protections in this bill. . . .

Mr. BAUCUS.

These beneficiary protections are crucial for these vulnerable Medicare beneficiaries. . . . If a plan can’t adequately ensure all of the proper medication for beneficiaries living with HIV/AIDS, epilepsy, and certain mental illnesses, that plan should not be doing business with Medicare. . . .

We note no mention here – or anywhere else in any recorded legislative history of the MMA and subsequent legislation that we have been able to identify – that Congress in any way believed the need for these protections to be temporary, as CMS asserts in the Proposed Rule.⁹ All commentary in the legislative record and CMS’ *own regulations*, prior to publication of the Proposed Rule, reference the vulnerability of the relevant patient populations as the rationale for the protected classes policy.

2. The Medicare Improvement for Patients and Providers Act Codified and Strengthened the Protected Classes Policy

Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) *strengthened* the protected classes policy by codifying it in the Part D statute, a strong congressional affirmation of the ongoing importance of these protections. Of greatest relevance, Congress rejected CMS’ “substantially all” standard for Part D plan coverage of these classes by requiring that “all” such therapies be covered.¹⁰ This strong endorsement and enhancement of the policy occurred less than two years prior to enactment of the ACA and section 3307.

⁹ Ibid.

¹⁰ 42 U.S.C. § 1395w-104(b)(3)(G)(ii).

3. The Patient Protection and Affordable Care Act Reiterated Congress's Support for the Protected Classes while Giving CMS Authority to *Improve Them*

Section 3307 of the ACA continued Congress' intense support for the protected classes policy by updating the relevant provisions of MIPPA.¹¹ After reiterating the requirement that Part D plans cover "all" drugs in a protected class, the ACA directed CMS to "identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern."¹²

As a first order matter, Congress gave no indication, in the text of the ACA or in the accompanying body of legislative history, or as captured by related third party analysis, that it intended section 3307 be used to weaken the protected classes policy. A reading of section 3307 in the context of the policy's initial enactment and subsequent endorsement in MIPPA, less than two years prior to the passage of the ACA, can only conclude that the provision was a continuation of Congress' strong support for the protected classes policy. In scoring the policy, the Congressional Budget Office assigned no savings to the provision, a clear reflection that Congress had no intent that it be used to weaken the protected classes policy in an effort to cut costs.¹³

Furthermore, Congress enacted section 3307 without modifying the Part D non-discrimination requirement in any way. Therefore, contemporaneous with passage of section 3307, Congress maintained the statutory provision that it and CMS both interpreted to *require* initiation of the protected classes policy in the first place. This is a clear signal that Congress intended that section 3307 serve as a platform for expanding and improving the baseline of protections initially effectuated under authority of the non-discrimination provisions of the MMA.

Ultimately, the clearest statement of Congress's intent in enacting section 3307 of the ACA comes from Congress itself. On February 5, 2014, every member of the Senate Finance Committee sent a letter to CMS Administrator Marilyn Tavenner rejecting the agency's approach to implementing the section, in no uncertain terms. Reiterating that "Congress and the Administration have recognized that for certain types of conditions and therapies beneficiaries should have access to all available medications" since the launch of Part D, Finance members "strongly urge" CMS "to continue this important beneficiary protection as it exists today."¹⁴

On March 4, 2014, the House Energy & Commerce and Ways & Means Committees followed suit, with 50 of the committees' members sharply rebuking CMS' proposed implementation of section 3307. The committee members explain that section 3307 "reaffirm[ed]" Congress's determination that the existing six classes were appropriate for the protected classes policy before noting that CMS' proposal "will place harmful limits on Medicare beneficiaries' access to necessary medications."¹⁵

B. Legislative Timeline Rebuts CMS Assertion that Circumstances Justifying Protected Classes Policy Have Changed

The linchpin of CMS' argument appears to be that circumstances for this vulnerable patient population have changed "dramatically" and that they are now somehow fluent in traversing utilization

¹¹ See 42 U.S.C. § 1395w-104(b)(3)(G).

¹² 42 U.S.C. § 1395w-104(b)(3)(G)(ii)(I).

¹³ <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf>

¹⁴ U.S. Senate Finance Committee, Letter to Administrator Tavenner (February 5, 2014).

¹⁵ U.S. House Ways & Means and Energy & Commerce Committees, Letter to Administrator Tavenner (March 4, 2014)

management techniques, including denial of physician-prescribed drugs at the point of sale, and Part D appeals processes. Understandably, CMS offers no evidence to support this proposition other than the passage of time.

Unfortunately, Medicare beneficiaries afflicted with conditions addressed by the protected classes continue to have considerable difficulty in navigating Part D. Many patients with mental illnesses such as depression, for example, have cognitive difficulties and lack motivation to confront obstacles to their care. Sound clinical evidence and the clear intent of Congress is that the protected classes policy will be necessary to ensure safe, appropriate care for currently covered populations for the foreseeable future. While we carry hope for a breakthrough in treatment of any of these conditions, the fact that it is difficult for these patients to traverse the complex hurdles put in their way to comply with their treatment regimens is unlikely to change.

Due to the legislative history of the relevant provisions, CMS must assume that Congress believed this dramatic turnaround in Medicare beneficiary proficiency in navigating the complex milieu of plan formulary structures and other utilization management techniques, as well as Medicare appeals process, occurred in less than two years.

CMS acknowledges that MIPPA, which was enacted on July 15, 2008, was a reaffirmation and expansion of the protected classes policy in place at that time, and was in the process of implementing regulations to that effect when the ACA was signed on March 23, 2010.¹⁶ But CMS's interpretation of section 3307 of the ACA in this Proposed Rule suggests Congress thought the MIPPA-affirmed policies were no longer necessary due to significant progress in beneficiary competence, even though initial drafting of the ACA began in the summer of 2009, *only one year after MIPPA passed*. This hardly seems like a sufficient amount of time for a "dramatic" change in the circumstances encompassing Medicare beneficiaries protected by the classes policy.

C. CMS' Emphasis on Cost Cutting Reverses Congress's Intent and Relies on Unsubstantiated Claims

1. Purpose of Section 3307 is to Safeguard Classes of Clinical Concern, Not Cut Costs

CMS' pursuit of unsubstantiated claims regarding costs and utilization reflect a fundamental misreading of section 3307 of the ACA, which was – in CMS' own words – “intended to provide additional beneficiary protections.”¹⁷ CMS turns the provision on its head by establishing a standard that shifts the burden of proof on those whose primary concern is patient care; the default assumption is that new barriers should be imposed.

CMS defines the standard this way: the protected classes policy should not apply “unless we cannot ensure clinically appropriate access ... in any less anticompetitive way.”¹⁸ This acrobatic double negative is clearly designed to generate an outcome that satisfies CMS' underlying motivation: restricting access as a way to cut costs. In its effort to strike a “balance among beneficiary access, quality assurance, cost containment and patient welfare,”¹⁹ CMS has unduly tipped the scale heavily in favor of the cost containment factor. Unlike the other considerations, for which there is a rich legislative history or support, there is no trace of evidence Congress ever factored cost implications into its authorship of section 3307,

¹⁶ 79 Fed. Reg. at 1937.

¹⁷ 79 Fed. Reg. at 1942.

¹⁸ 79 Fed. Reg. at 1938.

¹⁹ 79 Fed. Reg. at 1937-38.

which it understood would have *no* impact on the Federal budget at the time of passage.²⁰ To the contrary, in that section, whose title after all begins with “*Improving Formulary Requirements...*,” Congress specifically required the Secretary to identify classes of *clinical* concern, with no reference to cost cutting.²¹

Congress has soundly rejected CMS’s assumptions and the agency’s conclusion in this regard as well. In the February 5 letter to Administrator Tavenner, all Finance Committee members expressed their concern that “in an attempt to reduce Medicare costs, CMS is proposing to limit these protections.”²² The Committee further rejects CMS’s underlying cost-savings assumptions, citing ample support from the OIG and CBO for its conclusion that it is “unconvinced this change will lead to significant cost savings.”²³

2. CMS’ Savings Assumptions are Not Substantiated by the Reports it Cites

As delineated in Table 1, and as further discussed in Table 14 under section VI (Regulatory Impact Analysis (RIA)) of the Proposed Rule, CMS estimates that the proposed modifications to the protected classes would save the Part D program \$720 million over the CY 2015-2019 period.²⁴ CMS’ aggregate savings estimate is, by the agency’s own acknowledgement, predicated on the assumption of the “*full implementation*” of the criteria, as opposed to the manner in which CMS’ proposal was *actually promulgated*.²⁵ So the number is false on its face; CMS has justifiable hesitations – which call into question its savings assumptions – about removing antipsychotics, to which the agency attributes “most of these savings.”²⁶

Furthermore, the reports that CMS cites to suggest that the protected classes policy increases Part D costs fail to support the agency’s conclusion. Not one of the three reports actually presents data establishing that protected class drugs have higher prices or lower Part D rebates than comparable drugs in non-protected classes.

The 2011 HHS Office of Inspector General (OIG) report cited by CMS only repeats remarks of Part D plan representatives complaining about the rebates manufacturers paid on protected-class drugs.²⁷ These various “assertions” by Part D plan representatives are insufficient evidence to support putting patients at risk.²⁸

The Milliman report that CMS cites merely reflects the results of a survey the company conducted for the Academy of Managed Care Pharmacy (AMCP) asking for, again, the opinions of Part D plan representatives.²⁹ On its face, the survey instrument used for this “study” demonstrates clear bias, asking for the “opinions” of Part D plan sponsors on the “extent to which” (not “whether”) the protected classes policy prevents them from cutting costs, in part to build opposition to any expansion of the

²⁰ See CBO estimate for H.R. 3590 p. 8 (March 11, 2010), *available at* http://cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11307/reid_letter_hr3590.pdf.

²¹ 42 U.S.C. § 1395w-104(b)(3)(G)(ii)(I).

²² Letter to Administrator Tavenner at p. 1.

²³ *Ibid.*

²⁴ 79 Fed. Reg. at 2046.

²⁵ 79 Fed. Reg. at 2047.

²⁶ 79 Fed. Reg. at 2035.

²⁷ HHS OIG, Concerns with Rebates in the Medicare Part D Program, March 2011, OEI-02-08-00050.

²⁸ 79 Fed. Reg. at 1937-38.

²⁹ 79 Fed. Reg. at 1938.

policy.³⁰ Furthermore, on page one, the report itself notes that, while clinical outcomes related to use of therapies covered by the protected classes policy “are of greatest importance,” it focuses only on the “simple costs” associated with “customary drug management practices.”³¹

Finally, the study CMS cites that was published in the American Economic Review only examines the first year of Part D, focuses on “small” therapeutic classes, not the six protected classes per se, and, even then, its conclusion relating to price impacts are not statistically significant.³²

This lack of evidence is why MedPAC, in its March 2011 report to Congress, concludes that “it lacks rebate information” to determine whether “...the drugs’ protected status may keep plan sponsors from negotiating rebates from manufacturers in classes in which one brand-name drug can be a therapeutic substitute for another brand-name drug.”³³

3. CMS Ignores Countervailing Costs Associated with Destabilizing Patient Care

In addition, it is disconcerting that CMS’ aggregate savings estimate fails to assess the implications of the proposed Part D changes in their totality, i.e., by assessing potential cost-increasing and cost-shifting interactions within the broader Medicare program (Parts A and B), and to Medicaid. In CMS’ own words, limiting access to the most appropriate medications will drive higher costs in Medicare Parts A and B by increasing admittance to inpatient hospital care and EDs due to the destabilization of patients’ conditions. In previous guidance, the agency itself has indicated that “factors described in our formulary guidance indicated that interruption of therapy in these [protected] categories could cause significant negative outcomes to beneficiaries in a short timeframe.”³⁴

While the agency notes that, in some cases, manufacturers may make price concessions to keep these drugs on formularies, if negotiations are not successful, the agency states “we would expect sponsors to take these products off formulary,” with the result of, “either way, the beneficiary’s drug costs and costs to the program” would decrease.³⁵ The corresponding savings estimated to stem from restricting access makes no attempt, however, to quantify the beneficiary impact of such changes in modifying established treatment regimens, which may involve the weaning off dosages and re-titrating to the therapeutic level; delays in filling the new prescription; issues with tolerability of the new prescription – including the presentation of new, unforeseen side effects – or other barriers affecting the beneficiary’s propensity to adhere.

A variety of published clinical studies document the adverse impacts that ensue when beneficiaries with mental illness, for example, experience delays or discontinuation of appropriate care. Smith et al found that mental health patients whose psychotropic medications are discontinued may

³⁰ “Potential cost impacts resulting from CMS guidance on ‘Special Protections for Six Protected Drug Classifications’ and Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (PL 110–275),” Milliman (2008), at 1, available at: <http://amcp.org/WorkArea/DownloadAsset.aspx?id=9279> (emphasis added).

³¹ Ibid.

³² Duggan M, Morton FS, 2010. “The Effect of Medicare Part D on Pharmaceutical Prices and Utilization,” American Economic Review, American Economic Association, vol. 100(1), pages 590-607.

³³ http://www.medpac.gov/chapters/Mar11_Ch13.pdf.

³⁴ CMS, “Why is CMS requiring “all or substantially all” of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?” available at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/FormularyGuidanceAllorSubAll.pdf>.

³⁵ 79 Fed. Reg. at 2036.

relapse to more severe episodes and require psychiatric hospitalization.³⁶ Furthermore, disruptions in medication continuity among psychiatric patients are associated with high rates of symptom relapse or exacerbation, hospitalization, and other adverse consequences.³⁷ Patients who experienced an access problem were more likely to have an emergency department visit for the treatment of a psychiatric illness.³⁸

Furthermore, according to the American Society of Transplantation, inability to access proper immunosuppressive medications and combinations will lead to increased rates of chronic immune rejection characterized by organ injury, patient suffering and ultimately even death.³⁹ CMS' policy would also "dramatically increase the need and costs for constant drug level monitoring ... [and] the number of necessary patient visits to evaluate the changing therapies."⁴⁰

Additional research in the oncology space found that reduced use of necessary medicines increases the probability of having an ER visit and patients' health care costs.⁴¹ Recently, the Kaiser Family Foundation found, among other conclusions, that inadequate or lack of access to care often leads to adverse health outcomes.⁴²

For example, the Kaiser piece stated:

A ... study of Medicare beneficiaries found that savings from increasing copayments for physician services and prescription drugs led to additional costs from increased hospitalizations. For those in the worst health, the additional costs from increased hospitalizations were larger than the savings accrued from the increased copays for physician services and prescription drugs, with hospital spending increasing by nearly \$2 for every \$1 saved on other spending."⁴³

More broadly, the benefits of adequate access to necessary prescription drugs are well documented. CBO recently announced a change to their cost estimating methodology to reflect evidence showing that increases in prescription drug use lead to offsetting reductions in spending for medical services.⁴⁴ Specifically, CBO estimates that a one percent increase in the number of prescriptions filled by beneficiaries would cause Medicare's spending on medical services to fall by roughly one-fifth of one percent.⁴⁵

In its broad efforts to improve healthcare quality in other contexts, CMS has repeatedly emphasized the interlinked goals of improving efficiency while enhancing quality and patient experience. The agency notes in its 2013 Quality Strategy, for example, that "reducing costs goes hand-in-hand with

³⁶ Smith, Kenneth J. et. al., *Cost-Effectiveness of Medicare Drug Plans in Schizophrenia and Bipolar Disorder*, 19:2 Am J Manag Care 55 (2013).

³⁷ Huskamp, Haiden A., PhD. et. al., *Part D and Dually Eligible Patients with Mental Illness: Medication Access Problems and Use of Intensive Services*, 60:9 Psychiatric Services (2009).

³⁸ Ibid.

³⁹ American Society of Transplantation, Letter to CMS (February 18, 2014).

⁴⁰ Ibid.

⁴¹ Subramanian, S., 2011. Impact of Medicaid Copayments on Patients with Cancer: Lessons for Medicaid Expansion Under Health Reform. *Medical Care*, September, 49(9), p. 842-847.

⁴² Kaiser Family Foundation, *Premiums and Cost-Sharing in Medicaid: A Review of Research Findings* (Feb. 2013), available at <http://kaiserfamilyfoundation.files.wordpress.com/2013/02/8417.pdf>.

⁴³ Ibid.

⁴⁴ CBO "Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services." November 2012. <http://www.cbo.gov/publication/43741>.

⁴⁵ CBO "Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services." November 2012. <http://www.cbo.gov/publication/43741>.

the aims of expanding access, providing high-quality care, and promoting population health.”⁴⁶ The proposed roll-back of protected class safeguards, with its singular focus on efficiency, presents a contrast with this approach by undermining any potential efficiencies with poor quality of care.

Finally, CMS acknowledges its failure to quantify the increased costs to third-party Pharmacy Benefit Managers (PBMs) due to the potential for “increase[d] exception requests, appeals, prior authorizations, and outreach to Part D sponsors...”⁴⁷ But the ramifications of such an uptick in appeals would be far more significant than CMS’ references. Appeals volume would indeed increase and add to administrative costs, but CMS does not seem to contemplate the impact of the appeals process on beneficiaries, including those who have a legitimate appeal but decide to forego that avenue due to its complexity, cost of their time, or the sheer intimidation involved in objecting to a bureaucratically rendered decision. Those patients will instead go without needed treatment or experience a considerable gap in their care.

4. Part D Plans Already have Strong Cost Control Measures at their Disposal

Contrary to CMS’ suggestions in the Proposed Rule, Part D plans have strong incentives to reduce costs and have utilized an array of tools to manage drug utilization, such as tiered formularies, in the protected classes.

After asserting that the policy creates “essentially open coverage” of some drugs, CMS notes that the “principal disadvantage” of the protected classes policy is that it “substantially limits Part D sponsors’ ability to negotiate price ... and results in higher Part D costs.”⁴⁸

But Medicare Part D plans already manage utilization of drugs and exact manufacturer rebates under the current protected class policy. Under CMS guidance, for drugs other than those relating to HIV, Part D plans may use prior authorization and step therapy to manage therapies for any beneficiary just starting on a protected-class drug,⁴⁹ giving plans considerable discretion to limit access to more expensive drugs and considerable leverage to extract rebates from manufacturers.

Donahue et al found, for example:

Restrictions on psychotropic medications were common among the drug plans studied. Estimated rates of medication switching attributable to Medicare Part D were 6%-10% among dually eligible beneficiaries using antipsychotics, 5%-7% among those using antidepressants, and 2%-4% among those using mood stabilizers. Switching rates varied substantially across plans.⁵⁰

Furthermore, Part D Plans are allowed to tier the cost of these medications, which has proven effective in reducing drug costs. Research by MedPAC has shown that generic dispensing rates (GDR) are not artificially low in protected-class categories, finding that anticonvulsants in 2011 had a GDR of 86%, which was the third-highest GDR among the top-15 most commonly prescribed drug classes in the Part D program.⁵¹ Antidepressants also had an 83% GDR, compared with 77% across all therapeutic

⁴⁶ CMS Quality Strategy: 2013 and Beyond (November 18, 2013).

⁴⁷ 79 Fed. Reg. at 2036.

⁴⁸ Ibid.

⁴⁹ Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5.

⁵⁰ Donahue, Julie M. Ph.D. et. al., *Estimating Medicare Part D's Impact on Medication Access Among Dually Eligible Beneficiaries With Mental Disorders*, 58:10 *Psychiatric Services* (2007).

⁵¹ Medicare Payment Advisory Commission, “Data Book: Health Care Spending and the Medicare Program: Chapter 10—Prescription Drugs,” June 2013, p. 24, <http://www.medpac.gov/chapters/Jun13DataBookSec10.pdf>.

classes.⁵² This is the case despite the fact that individuals requiring more expensive or brand name medications are ensured access without appeal under existing protected classes policy.

II. CMS' New Policy Puts Patients at Risk and Lacks any Clinical Support

A. First Prong of New Standard Fails to Acknowledge Vulnerability of Impacted Patient Populations

Building on the foundation of a reading of section 3307 that sharply deviates from Congress's intent to protect patients, CMS proceeds to specify a new standard for identifying "clinical classes of concern" that can only be justified as a way to restrict access and cut costs.

CMS proposes:

In the case of a typical beneficiary who has a disease or condition treated by drugs in the following category or class, hospitalization, persistent or significant incapacity or disability, or death likely will result if initial administration ... of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled.⁵³

Notably, CMS does not cite a single clinical source for establishing this "seven day rule." Rather, the agency appears to base this standard on its faulty assumptions about the timeline and efficacy of the Medicare appeals process, which is examined in more detail below.⁵⁴

The first flaw in CMS' development of this new standard relates to orienting the policy toward the needs of a "typical" patient who "has the average clinical presentation of the relevant disease or condition."⁵⁵ On its face, this standard puts more vulnerable patients at risk. Furthermore, no patient with mental illness, in need of a transplant, or living with HIV, cancer or epilepsy is typical; they have complex, varying clinical needs that cannot be regressed to a mean.

Mental health patients, for example, tend to have high rates of comorbid chronic physical conditions such as heart disease and diabetes, which can be exacerbated by untreated mental illness.⁵⁶ Other risk factors include obesity, metabolic syndrome and stroke.⁵⁷

Furthermore, in isolating its analysis solely to the conditions respectively implicated by the protected classes policy, the Proposed Rule fails to recognize interrelatedness of diseases. For example:

- Nearly half of individuals receiving HIV treatment also have mental illness.⁵⁸
- One in four individuals with cancer has clinical depression.⁵⁹

⁵² Ibid.

⁵³ 79 Fed. Reg. at 1941.

⁵⁴ Ibid.

⁵⁵ Ibid.

⁵⁶ Smith, Kenneth J. et. al., *Cost-Effectiveness of Medicare Drug Plans in Schizophrenia and Bipolar Disorder*, 19:2 Am J Manag Care 55 (2013).

⁵⁷ Brunner, Eric J., *Depressive Disorder, Coronary Heart Disease and Stroke: Dose-Response and Reverse Causation Effects in the Whitehall II cohort Study*, 21:3 European Journal of Preventative Cardiology (2014).

⁵⁸ EG Bing et al., *Psychiatric Disorders and Drug Use Among Human Immunodeficiency Virus-Infected Adults in the United States*, *Archives of General Psychiatry*, August 2001, <http://www.ncbi.nlm.nih.gov/pubmed/11483137>.

- Depression is the “most frequent comorbid psychiatric disorder” in epilepsy, with a “risk of suicide [that] has been estimated to be 10 times higher than that in the general population...”⁶⁰
- A systematic evidence review and meta-analysis of 23 articles drawing on 14 data sources found the incidence of active depression in people with epilepsy, on average, to be 23.1%.⁶¹

As outlined above, by diminishing certain elements of these patients’ care, CMS jeopardizes their compliance and their success in managing other conditions with which they live.

CMS’s dismissal of bona fide (and long-held) patient safety and care concerns is belied by its reference to the “inconvenience” of access delays not outweighing the need for restricted formularies. We would never assert, nor have we observed any others claim, that the protected classes policy relates in any way to convenience. Jeopardizing care for patients with serious clinical conditions during whatever arbitrary gap in access CMS would willingly impose is a much deeper concern than that.

CMS’ most fundamental misstep, though, is assuming that any intentional delay of needed therapies is safe for patients with conditions covered by the existing protected classes policy. Even minor delays in care can have dire consequences for these patients. While many patients will face these consequences, ranging from hospitalization to death, that is – regardless – a deplorable benchmark for how well Part D is meeting their needs.

Equally concerning is CMS’ promotion of the Department of Defense (DoD) and Veterans Administration (VA) formularies as adequate to ensuring patients’ access to necessary medications.⁶² This is a truly disturbing reference; the deeply unfortunate challenges faced by our nation’s soldiers and veterans in obtaining successful treatment for their mental health needs, for example, is well documented and pervasively deployed.

The goal of prescription therapies for these populations is to sustain good health and prevent declines that warrant acute care. The current protected classes policy ensures maintenance of this standard. CMS’ proposal would eviscerate it in favor of a minimum standard that would upset the balance of these patients’ treatment in unverified hopes that fallback protections will succeed in avoiding catastrophic outcomes.

B. Second Prong of New Standard is Biased and Contradicts Clinical Standards

1. The Second Prong is Biased in Favor of Restricting Access

After stating that CMS’ new “seven day rule” would not do enough to restrict access to medically necessary therapy, the agency imposes an even more vague and arbitrary prong to the new standard. It appears to be added solely to ensure the removal of some of the existing classes. In doing so, CMS

⁵⁹ American Cancer Society website, accessed Feb. 14, 2014, <http://www.cancer.org/treatment/treatmentsandsideeffects/physicalsideeffects/dealingwithsymptomsathome/caring-for-the-patient-with-cancer-at-home-depression>.

⁶⁰ AM Kanner, Depression in Epilepsy: Prevalence, Clinical Semiology, Pathologic Mechanisms and Treatment, ” *Biological Psychiatry*, August 2003, *available at* <http://www.ncbi.nlm.nih.gov/pubmed/12893113>.

⁶¹ KM Feist et al., “Depression in Epilepsy : A Systematic Review and Meta-Analysis,” *Neurology*, February 5, 2013, *available at* <http://www.neurology.org/content/80/6/590.short?sid=8f0120af-36cb-4f15-aa01-da68c578bb47>.

⁶² 79 Fed. Reg. at 1946.

abandons sound clinical practice and takes another distinct step afield of Congress' intent that the agency develop a standard that strengthens existing patient protections.

This prong reads:

More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or conditions manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.⁶³

Here CMS again reasserts its bias in favor of implementing a policy that restricts access by introducing the requirement that, "in the absence of any specific treatment guidelines to the contrary," inclusion of all drugs in a class is unnecessary. CMS has embedded a presumption that the protected classes policy should be weakened and that some currently covered drugs should be removed. As the agency rationalizes, in the portion of the Rule addressing its consideration of alternative policies, "only narrow criteria would limit the number of categories or classes of clinical concern receiving additional protections under the [ACA]."⁶⁴ CMS strangely implies that, in this case, the agency's ends justify its otherwise indefensible means.

2. CMS' Standard Neglects Variation of Patient Response to Treatment and is Directly Refuted by the Clinical Sources it Cites

A key element of CMS' faulty conjugation of this standard is its reliance on inaccurate characterizations of what constitutes interchangeability and variation of patient response.

Individuals benefiting from the protected classes policy require access to a broader variety of drugs than patients with less acute or nuanced illnesses to ensure appropriate care. According to a *Health Affairs* study, "In treating mental illnesses, patients and physicians typically work through a trial-and-error process to identify the best medication or medication combination... This complicates formulary-driven medication switches. Unlike other chronic conditions such as hyperlipidemia, hypertension, and osteoporosis, disrupting psychiatric medications can have immediate health consequences resulting in symptoms, functional impairment, and accelerated use of health services."⁶⁵

Additional research documents that, while a specific medication may help one individual, it may not help another with the same diagnosis. No single mental health medication, for example, works for all patients and there may be various side effects that one person experiences versus another.⁶⁶

The federally funded STAR*D study found that, while about one in three will get better on the first treatment they receive for depression, many individuals will need to keep trying different treatment regimens or combinations to get better.⁶⁷ According to one of the STAR*D researchers, the study

⁶³ 79 Fed. Reg. at 1942.

⁶⁴ *Ibid.*

⁶⁵ NP Morden and LE Garrison. "Implications of Part D for Mentally Ill Dual Eligibles: A Challenge for Medicare." *Health Affairs*, 2006 Mar-Apr; 25(2):491-500.

⁶⁶

http://www.nami.org/Template.cfm?Section=Access_to_Medications&Template=/ContentManagement/ContentDisplay.cfm&ContentID=47683

⁶⁷ National Institutes of Health, National Institute of Mental Health, "Switching to a Third Antidepressant Medication May Prove Helpful to Some with Treatment-resistant Depression," (2006), *available at* <http://www.nimh.nih.gov/press/stard3.cfm>.

provides important information that intolerance or lack of efficacy with one SSRI antidepressant does not seem to predict the same with another.⁶⁸

In the mental health space, though, the definitive refutation of CMS' clinical propositions comes from the American Psychiatric Association (APA), whose guidelines CMS cites to justify undermining the protected classes policy for these patients.⁶⁹ The APA states concisely: "CMS misrepresents APA's relevant practice guidelines."

CMS' "selective quoting" of the APA's "guidelines and flawed clinical logic apparently led [the agency] to conflate the supposed 'interchangeability' of drugs within the classes of both antidepressants and antipsychotics with overall evidence for efficacy," the Association writes, "when this is just one element of a drug's appropriateness for an individual patient."

In fact, the "APA guidelines that address the use of antidepressants and antipsychotics ... all recommend the *opposite* of CMS's interpretation." (emphasis added) In sum, the agency "misinterprets and misrepresents APA's clinical practice guidelines multiple times as justification for limiting patient access to medically necessary psychotropic medications."

With its references to APA guidelines indisputably and definitively refuted, CMS' proposals impacting mental health therapies have absolutely no foundation in sound clinical science.

CMS' analysis of immunosuppressive therapies is similarly flawed and contrary to widely accepted clinical evidence. Immunosuppressants are prescribed in combinations tailored to meet the unique needs of the individual transplant recipient in order to achieve sufficient immunosuppression while minimizing the toxicity associated with individual agents.⁷⁰ Restrictive, one-size-fits-all formularies limit physicians' ability to prescribe the right combination of medications to protect the recipient from organ rejection and other serious side-effects.

As articulated by the American Society for Transplantation:

[T]imely access to immunosuppressants is critical for patients with transplanted organs. ... [C]urrent immunosuppressive therapies in transplantation are based on the use of multiple drugs whose mechanisms are complimentary. ... Each agent has different toxicities, and each drug affects the action and efficacy of the other agents in the combination. ... Thus, it is simply impossible to safely switch back and forth between individual drugs in the combinations without completely reevaluating the whole combination.⁷¹

⁶⁸ National Institutes of Health, National Institute of Mental Health, "New Strategies Help Depressed Patients Become Symptom-Free," (2006), *available at* <http://www.nimh.nih.gov/press/stard2.cfm>.

⁶⁹ American Psychiatric Association, Letter to leaders of the House Energy & Commerce Committee (Feb. 25, 2014).

⁷⁰ National Kidney Foundation, "Managing Your Adult Patients who have a Kidney Transplant" (2009), *available at* https://www.kidney.org/professionals/tools/pdf/02-50-4079_ABB_ManagingTransRecipBk_PC.pdf. See also <http://www.ncbi.nlm.nih.gov/pubmed/12392286> and <http://www.ncbi.nlm.nih.gov/pubmed/18466104>.

⁷¹ Letter to CMS (Feb. 18, 2014).

C. Appeals Processes and other “Protections” are Inadequate to Ensure Patient Care

1. Reliance on Flawed Appeals Process Poses Significant Hazards

CMS erroneously relies on the *intended* regulatory timeframe for coverage determination and appeals processes to conclude in a satisfactory manner. First of all, there is strong reason to believe existing appeals processes are inadequate to ensure meaningful protections for this vulnerable population, much less within the timeframe CMS presumes. It is telling that the agency provides no data documenting that the exceptions process works in the manner it suggests in the Proposed Rule.

To the contrary, in a September 12, 2013, presentation, MedPAC staff identified significant, deep-seeded flaws with Part D exceptions and appeals processes.⁷² Among MedPAC’s findings:

- “A majority [of beneficiaries] did not know they had appeal rights ...;”
- Counselors urged beneficiaries to pursue an exception or appeal only as a last result, prioritizing switching plans (if possible), seeking samples, etc., instead ...;
- “CMS’ [own] audit in 2012 found that plans are struggling most with Part D coverage determination, appeals, and grievances ...;”
- “Examples of the kinds of issues identified include:
 - “Failure to make timely coverage determinations;
 - “Failure to notify the beneficiaries of their coverage decisions;
 - “Not making sufficient effort to obtain information needed to make an appropriate clinical decision ...;”
- “A large share of [appeal] dismissals due to technical reasons suggests enrollees may be confused or are having difficulty navigating the appeals process ...;
- “Majority of cases are reversed by the [Independent Review Entity (the 2nd appeal level)] ... suggest[ing] that there may be issues with the process used by plans to verify enrollees’ prior drug coverage status.”⁷³

This is the system that CMS would rely on to protect seniors and other beneficiaries with acute mental health needs or other serious illnesses from denied access to medications that can save their lives or prevent other adverse health outcomes. We respectfully submit that the Medicare Part D appeals process and other fallback protections CMS cites are, at present, woefully inadequate to even begin a conversation about their serving as a replacement for the protected classes policy.

For more than a decade, the OIG has documented concerns with the Medicare appeals process. In a 2002 report focused on Part B appeals, for example, the OIG noted that “the current Medicare appeals system is backlogged, overwhelmed, and untimely...”⁷⁴ As recently as last October 2013, the OIG’s assessment of volume, outcomes, and timeliness of the first level of the Medicare appeals process reflected its longstanding concerns.⁷⁵ OIG has also recently suggested that significant improvements are needed at the Administrative Law Judge level of Medicare appeals, including those under Part D, due to inconsistent approaches and differing interpretations of Medicare guidance.⁷⁶

⁷² Sokolovsky, Suzuki and Metayer, “Part D Exceptions and Appeals” (Sept. 12, 2013), *available at* <http://www.medpac.gov/transcripts/part%20d%20exceptions%20&%20appeals.pdf>.

⁷³ *Ibid.*

⁷⁴ <https://oig.hhs.gov/oei/reports/oei-04-01-00290.pdf>.

⁷⁵ <https://oig.hhs.gov/oei/reports/oei-01-12-00150.pdf>.

⁷⁶ <https://oig.hhs.gov/oei/reports/oei-02-10-00340.pdf>.

Current appeals process failures, in part the result of high volume, also do not account for the inevitable increase in appeals that are certain to happen due to CMS' proposal to restrict access to medically necessary medications under this proposed regulation.

In guidance provided to plan sponsors upon originally implementation of the protected classes policy, the agency posed, "Why is CMS requiring 'all or substantially all' of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?" Then it answered: "In the process of reviewing the practices of other Federal programs for comparable populations such as the Federal Employees Health Benefit Program (FEHB) and Medicaid, we learned that formulary inclusion rather than an exceptions process is an appropriate standard in certain circumstances."⁷⁷ CMS offers only tangential theories, but no evidence, to suggest that there is any reason to believe this assertion is no longer true.

2. Additional Fallback "Protections" CMS Cites are Inapposite and None Have Ever been Deemed Sufficient for this Population

CMS' enumeration of existing additional Part D "protections" in the Proposed Rule constitutes another emblem of the agency's misinterpretation of section 3307.⁷⁸ The majority of these protections were in place at the time Part D was launched, at which time CMS itself instituted the protected classes policy. Furthermore, they were in place and had been functioning for several years when Congress codified the protected classes policy in MIPPA and reaffirmed it in the ACA. There is no reason to think, and CMS offers no evidence to support, that these protections have ever been deemed sufficient by any policymaker to ensure the safety and quality of care for patients impacted by the classes policy.

Furthermore, and to reiterate previous points, it is clear from the data CMS presents here that their formulary review process is ineffective in providing access to needed medications for complicated diseases. For persons with mental illness, the agency's standard formulary review process would only require coverage of nine generic antidepressant and six generic antipsychotic medications, for a total of only 15 medications and no branded drugs.⁷⁹ In comparison, the existing protected classes policy entitles Medicare beneficiaries to access to 57 medications: 23 generic antidepressants, seven branded antidepressants, 18 generic antipsychotics and nine branded antipsychotics. CMS' analysis offers little assurance that this unprecedented restriction of access for this patient population will not yield harmful consequences for innumerable beneficiaries.

We will not address each protection volunteered by CMS, but we must point out that CMS appears to have aggregated a bundle of policies in an attempt to show robust protections when closer scrutiny reveals they are plainly insufficient to meet the needs of these populations. For example, CMS cites the "discrimination review" policy but notes it only is invoked to ensure coverage of "categories and classes used to treat all disease states."⁸⁰ As cited by CMS, the policy does nothing to recognize the nuances of care needs among the patients at stake here, which was in fact the foundation for layering the protected classes policy on top of the non-discrimination policy to begin with. CMS goes on to cite patently unrelated provisions, such as those regarding vaccine review and insulin supplies, which are not meaningfully implicated by the protected classes policy.

⁷⁷ CMS, "Why is CMS requiring "all or substantially all" of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?" <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/FormularyGuidanceAllorSubAll.pdf>.

⁷⁸ 79 Fed. Reg. at 1938-1941.

⁷⁹ Ibid.

⁸⁰ 79 Fed. Reg. at 1939.

D. Extension of CMS' Specious Logic Jeopardizes All Classes

We find it difficult to comment on the portion of the Proposed Rule that applies an irreparably flawed standard to determine the qualification of drugs for the protected classes policy. While CMS appropriately concludes that antiretrovirals, antineoplastics and anticonvulsants warrant inclusion among the protected classes, the agency demonstrates an under-appreciation of the vulnerability of patients who rely on antidepressants, antipsychotics and immunosuppressants for a critical aspect of their care and raises serious questions about the ongoing application of these protections to any drug class.

The highly vague, subjective and conclusion-in-mind nature in which CMS has developed and applied this new standard raises serious concerns that additional classes will be excluded in the future. CMS does not lend the faintest hint that it intends to in fact fulfill the intent of Congress by improving and expanding the protected classes in any way.

E. Expansion of Exceptions Further Weakens What's Left of the Protected Classes Policy

In light of the drastic, sweeping changes CMS has proposed to the protected classes policy, and the minimal time allowed for consideration of stakeholder responses to the Proposed Rule, we strongly urge the agency to take no further steps to jeopardize patient care by introducing new exceptions to whatever protections remain. Emblematic of this portion of the Proposed Rule is CMS' casual acknowledgement that prior authorization for new starts will delay access to initial therapy, in conflict with the first prong of the weakened standard the agency itself proposes. But CMS simply endorses this component, citing the need of Part D plans to have yet another tool to cut costs.⁸¹

F. Use of Call Letter Process is Insufficiently Thorough to Make Changes to Protected Classes Policy

We would also like to express our opposition to CMS' conclusion that it may use the annual Call Letter cycle to change the classes of clinical concern. While the timeline of this Proposed Rule, alone, fails to afford stakeholders and CMS itself sufficient time to respond to these grave changes before finalization of CY15 Part D policy will be necessary, the Call Letter cycle unquestionably fails to do so. The approximate 40 days between issuance of the Advance Notice and the Final Call Letter is far less than half of the standard timeframe for the standard notice and comment rulemaking Congress references in section 3307, which requires the Secretary to "establish the criteria [for identifying protected classes] and any exceptions . . . through the promulgation of a regulation which includes a public notice and comment period."⁸² It is impossible for CMS to carefully collect, review and react to comments on such a complicated and sensitive matter as removing these fundamental protections for vulnerable Medicare beneficiaries.

IV. Conclusion

The Partnership for Part D Access truly appreciates this opportunity to respond to CMS' Proposed Rule and the agency's consideration of the concerns we raise here. We are organizations committed to improving the health and welfare of individuals living with the serious conditions at stake, and we aim at all times to serve as constructive partners to CMS and other government entities pursuing the same goals.

⁸¹ 79 Fed. Reg. at 1944.

⁸² 42 U.S.C. § 1395w-104(b)(3)(G)(iii).

In this instance, however, we can contemplate no viable pathway to redeeming the portions of the Rule that address the protected classes policy. By unapologetically focusing on costs, relying on entirely unfounded assumptions at that, CMS has fundamentally misinterpreted the intent of section 3307, which was to *protect* patients in areas of clinical concern.

The criteria established in the process are not just vague and contrary to broadly accepted clinical standards, they appear to be justified only by their ends: diminishing the protected classes policy and restricting vulnerable beneficiaries' access to needed medications.

There is no conscionable resolution of the issues raised by these draft provisions – for the patients who have relied on the protected classes policy and the organizations who support and serve them – but to **rescind these components of the Proposed Rule in their entirety and implement section 3307 in a manner that, at minimum, guarantees the same degree of protection present before the Proposed Rule was issued.**

Sincerely,

The Partnership for Part D Access

The AIDS Institute | Alkermes | American Kidney Fund | American Osteopathic Association | Anxiety and Depression Association of America | Cancer Support Community | Community Access National Network | Depression and Bipolar Support Alliance | Essential Health Benefits Coalition | Epilepsy Foundation | Forest Laboratories | The Janssen Pharmaceutical Companies of Johnson & Johnson | Lennox-Gastaut Syndrome Foundation | Leukemia and Lymphoma Society | Lundbeck | Mental Health America | National Alliance of State and Territorial AIDS Directors | National Alliance on Mental Illness | National Council for Behavioral Health | National Kidney Foundation | Parkinson's Action Network | Sunovion | Takeda | Transplant Recipients International Organization | Women Against Prostate Cancer