National Alliance on Mental Illness

March 7, 2014

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

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)

On behalf of the National Alliance on Mental Illness (NAMI), I am writing to submit comments to CMS on the Proposed Rule titled, "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (the Proposed Rule). NAMI is the nation's largest organization representing people living with serious mental illness and their families. Through NAMI's 1,100 affiliates in all 50 states, NAMI is engaged in education, support and advocacy to improve the lives of children and adults living with mental illnesses such as schizophrenia, bipolar disorder, major depression, borderline personality disorder and severe anxiety disorders.

Since its inception, NAMI has supported the Medicare Part D program and worked to ensure its full implementation in serving both elderly and non-elderly beneficiaries living with mental illness. It is therefore disappointing that we write to urge CMS to pull back major portions of the Proposed Rule as counter to the interests of beneficiaries living with serious and chronic health conditions such as serious mental illness.

Medications are an integral component of effective treatment for people living with serious mental illness such as schizophrenia, bipolar disorder and major depression. The consequences of not having access to the right medications can be calamitous for these individuals. These may include: loss of employment, hospitalizations, homelessness, criminal justice involvement, or even death. As one person who wrote to us after the proposed rule was published expressed, "it took my doctor close to a year to find a medication that worked. Without that medication, I would have been confined to silent suffering in a hell that only those afflicted with similar conditions can imagine."

CMS should carefully review the legislative history pertaining to Medicare Part D because a close reading reveals that the legislative directive was to identify classes of *clinical* concern not to target classes of alleged *cost* concern. Furthermore, the studies cited by the agency do not support the conclusion that substantial savings will be achieved through the imposition of restrictions on certain classes of medication. NAMI urges CMS to consider the substantial spending associated with the destabilization of the patient care that implementation of the proposed rule will precipitate. The patient safeguards embedded in the protected classes continue to be necessary to protect access to needed medications; the standards proposed in the rule are ambiguous and rely upon fallback protections whose unreliability has been documented by government sources and whose inadequacy has been reflected in the lived experience of individuals and their families. Accordingly, we respectfully **recommend that this entire portion of the Proposed Rule be rescinded.**

I. Congress Intended to Protect Patients by Strengthening the Classes of Clinical Concern

A. Legislative History Demonstrates Congressional Intent to Protect Existing Classes

I. 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.[1] 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."[2] CMS reiterated this rationale in the Proposed Rule itself.[3] Consistent with that rationale, CMS policy protected access to: anticonvulsants; antidepressants; anti-neoplastics to treat cancer; antipsychotics; anti-retrovirals for HIV/AIDS; and immune-suppressants to prevent rejection of transplanted organs.[4]

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. Congress expressed significant concern regarding the needs of Medicare beneficiaries with mental illness, as illustrated in the Conference Report that accompanied the MMA.[5] 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]."[6]

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.[7] The colloquy pointed to the role of Part D's non-discrimination provision in protecting beneficiaries with these types of illness. The exchange between the 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.

[1] 79 Fed. Req. at 1937.
[2] Prescription Drug Benefit Manual, Ch. 6 § 30.2.5.
[3] 79 Fed. Reg. at 1937.
[4] Ibid.
[5] 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.
[6] H.R. Rep. 108-391 at 770.
[7] 149 Cong. Rec. S5882-03.

> 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. …

It is important to consider that there is 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.[8]

1. 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.[9] This strong endorsement and enhancement of the policy occurred less than two years prior to enactment of the Patient Protection and Affordable Care Act (ACA) and Section 3307.

2. The Patient Protection and Affordable Care Act (ACA) Reiterated Congress's Support for the Protected Classes while Giving CMS Authority to *Expand* Them

Section 3307 of the ACA continued Congress' intense support for the protected classes policy by updating the relevant provisions of MIPPA.[10] 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."[11]

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 to be used to weaken the protected classes policy. A reading of Section 3307 in the historical context of the policy's initial enactment and subsequent endorsement in MIPPA, less than two years prior to the passage of the ACA,

[8] Ibid.
[9] 42 U.S.C. § 1395w-104(b)(3)(G)(ii).
[10] See 42 U.S.C. § 1395w-104(b)(3)(G).
[11] 42 U.S.C. § 1395w-104(b)(3)(G)(ii)(I).

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 (CBO) 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.[12]

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. This is a clear signal that Congress intended that Section 3307 serve as a platform for expanding and improving the baseline of protections effectuated under authority of the non-discrimination provisions of the MMA.

Ultimately, the clearest statement of Congress' 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 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."[13]

B. The Legislative Timeline Indicates that Circumstances Justifying Protected Classes Policy Have Not Changed

NAMI is concerned that there appears to be an assumption in the proposed rule that circumstances for this vulnerable patient population have changed "dramatically" and that they are now fluent in traversing utilization management techniques, including denial of physician-prescribed drugs at the point of sale, and Part D appeals processes. However, there does not appear to be evidence to support this proposition other than the passage of time and it is not supported by the experience of the affected individuals.

Unfortunately, Medicare beneficiaries living with mental illness and other serious conditions addressed by the protected classes continue to have considerable difficulty in navigating Part D. Many live with cognitive and other challenges and lack the ability to confront obstacles to their care. Sound clinical evidence and the 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. The fact that it is difficult for these patients to traverse complex hurdles put in their way has not changed and is unlikely to change.

C. Congress Intended to Safeguard Classes of Clinical Concern

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

As CMS notes, Section 3307 of the ACA was "intended to provide additional beneficiary protections."[14] The proposed rule 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.

The proposed rule defines the standard this way: the protected classes policy should not apply "unless we cannot ensure clinically appropriate access … in any less anticompetitive way."[15] This proposed policy is

[12] http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf
[13] U.S. Senate Finance Committee, Letter to Administrator Tavenner (February 5, 2014).
[14] 79 Fed. Reg. at 1942.
[15] 79 Fed. Reg. at 1938.

clearly designed to cut costs, rather than preserve clinical judgment. While we understand the goal of striking a "balance among beneficiary access, quality assurance, cost containment and patient welfare,"[16] this standard unduly tips 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 evidence Congress ever factored cost implications into its authorship of Section 3307, which it understood would have *no* impact on the Federal budget at the time of passage.[17] 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.[18]

In the February 5 letter to Administrator Tavenner, all Senate Finance Committee members expressed their concern that "in an attempt to reduce Medicare costs, CMS is proposing to limit these protections."[19] The Committee further rejects the underlying cost-savings assumptions, citing ample support from the U.S. Department of Health and Human Services Office of Inspector General (OIG) and CBO for its conclusion that it is "unconvinced this change will lead to significant cost savings."[20]

2. The Savings Assumptions in the Proposed Rule Should Be Reconsidered

CMS estimates that the proposed modifications to the protected classes would save the Part D program $720 million over the CY 2015-2019 period.[21] As the agency indicates, this aggregate savings estimate is predicated on the assumption of the *full implementation* of the criteria, as opposed to the manner in which the proposal was *actually promulgated*.[22] We urge CMS to consider the importance of this distinction. "[23]

Moreover, NAMI urges CMS to consider further the lack of support in the reports cited for the new rule. Not one of the three reports presents data establishing that protected class drugs have higher prices or lower Part D rebates than comparable drugs in non-protected classes. For example, the 2011 OIG report and the Millman report rely on assertions and opinions by Part D representatives and are insufficient evidence to support putting patients at risk.[25]

Finally, the study 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.[28]

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."[29]

3. CMS Should Focus on Countervailing Costs Associated with Destabilizing Patient Care

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[16] 79 Fed. Reg. at 1937-38.
[17] 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.
[18] 42 U.S.C. § 1395w-104(b)(3)(G)(ii)(I).
[19] Letter to Administrator Tavenner at p. 1.
[20] Ibid.
[21] 79 Fed. Reg. at 2046.
[22] 79 Fed. Reg. at 2047.
[23] 79 Fed. Reg. at 2035.
[25] 79 Fed. Reg. at 1937-38.
[28] 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.
[29] http://www.medpac.gov/chapters/Mar11_Ch13.pdf.

The aggregate savings estimate of the rule 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. As CMS has acknowledged, 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 emergency departments due to the destabilization of patients' conditions. In previous guidance the agency 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."[30]

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 that "either way, the beneficiary's drug costs and costs to the program" would decrease.[31] 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 plans, 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 desire and ability to continue with needed medications and goals that are supported by the treatment plan.

NAMI fully supports shared decision-making which involves a thoughtful discussion between individuals and physician of the person's goals and how medication fits into those goals. These discussions carefully consider the factors listed above before arriving at the right medication as part of a plan for recovery. This policy would ignore that careful planning and override the person and doctor's choices to the detriment of the patient and with the increased likelihood that they will no longer follow the plan.

A variety of published clinical studies document the adverse impacts that ensue when beneficiaries living with serious mental illness experience delays or discontinuation of appropriate care. Smith et al found that people with mental illness whose psychotropic medications are discontinued may relapse to more severe episodes and require psychiatric hospitalization.[32] Furthermore, disruptions in medication continuity among people with mental illness are associated with high rates of symptom relapse or exacerbation, hospitalization, and other adverse consequences.[33] Patients who experienced an access problem were more likely to have an emergency department visit for the treatment of a psychiatric illness.[34]

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.[35] Specifically, CBO estimates that a one percent increase in the number of prescriptions filled by

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[30] 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.

[31] 79 Fed. Reg. at 2036.

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

[33] 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).

[34] Ibid.

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

beneficiaries would cause Medicare's spending on medical services to fall by roughly one-fifth of one percent.[36]

In its broad efforts to improve healthcare quality, 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 the aims of expanding access, providing high-quality care, and promoting population health."[37] The proposed roll-back of protected class safeguards, for 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…"[38] But the ramifications of such an uptick in exceptions and appeals would be far more significant. Appeals volume would indeed increase and add to administrative costs. 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. This is particularly true for individuals living with serious mental illness who frequently experience cognitive impairments and lack the supports necessary to negotiate complex appeals processes. Those individuals will instead go without needed treatment or experience a considerable gap in their care.

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

NAMI would urge that CMS reconsider its view of the current incentives that Part D plans have to reduce costs. Plans have utilized an array of tools to manage drug utilization, such as tiered formularies, in the protected classes. In support of the proposed rule, 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."[39]

However, Medicare Part D plans already manage utilization of drugs and exact manufacturer rebates under the current protected class policy. Under CMS guidance, Part D plans may use prior authorization and step therapy to manage therapies for any beneficiary just starting on a protected-class drug,[40] giving plans considerable discretion to limit access to more expensive drugs and considerable leverage to extract rebates from manufacturers of protected-class drugs. 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 percent-10 percent among dually eligible beneficiaries using antipsychotics, 5 percent-7 percent among those using antidepressants, and 2 percent-4 percent among those using mood stabilizers. Switching rates varied substantially across plans.[41]

Furthermore, Part D plans are allowed to tier the cost of these medications, which has proven effective. Research by MedPAC has shown that generic dispensing rates are not artificially low in protected-class

[36] CBO "Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services." November 2012. http://www.cbo.gov/publication/43741.
[37] CMS Quality Strategy: 2013 and Beyond, November 18, 2013.
[38] 79 Fed. Reg. at 2036.
[39] Ibid.
[40] Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5.
[41] 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).

categories, finding that anticonvulsants in 2011 had a GDR of 86 percent that was the third-highest GDR among the top-15 most commonly prescribed drug classes in the Part D program.[42] Antidepressants also had an 83 percent GDR, compared with 77 percent across all therapeutic classes.[43] Though importantly, individuals requiring more expensive or brand name medications are ensured access without appeal under existing protected classes policy.

II. If the Proposed Rule is Implemented, Patients Would Be Placed at Risk

A. It is Critical to Consider the Vulnerability of Impacted Patient Populations

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.*[44]

NAMI is concerned that this "7 day rule" will place individuals with mental illness at risk. The standard set forth in the rule is based on the needs of a "typical" patient who "has the average clinical presentation of the relevant disease or condition."[45] The assumption that there is a "typical" patient with mental illness is erroneous. People living with mental illness have complex, varying clinical needs that cannot be characterized as typical. Treatment needs vary from person to person.

As one person who communicated with NAMI said, "Different people respond to different medications differently. It is not a one size fits all. It took 10 years for me to find the right balance of medication and I had a very skilled doctor that cared and a lot of medications to choose from until we got it right."

This is certainly the case with respect to the more than 9 million non-elderly Medicare beneficiaries. These beneficiaries who qualify for the program as a result of being eligible for Social Security Disability Insurance (SSDI) have already met a high standard of functional impairment – namely, below Substantial Gainful Activity (SGA) likely to last more than 12 months. These individuals should not be characterized as "typical" patients with predictable clinical characteristics. It is also important to recognize that Part D beneficiaries who will potentially be impacted by these proposed changes are not newly diagnosed indivduals for whom treatment is first being initiated. Non-elderly beneficiaries living with serious mental illness are likely to have been living with disorders such as schizophrenia, bipolar disorder and major depression for years before becoming eligible for Part D – through the long process of SSDI claims adjudication and a 24-month waiting period for Medicare eligibility. During this period these individuals have already likely gone through trial and error with various medications. To further limit therapeutic options creates significant risks for these individuals.

It is also important to recognize that many Part D beneficiaries living with serious mental illness have high rates of comorbid chronic physical conditions such as heart disease, asthma, diabetes and COPD

[42] 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.
[43] Ibid.
[44] 79 Fed. Reg. at 1941.
[45] Ibid.

that are often exacerbated by untreated mental illness.[46] Other risk factors include obesity, metabolic syndrome and stroke.[47]

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.[48]
- One in four individuals with cancer has clinical depression.[49]
- 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…"[50]
- 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 percent.[51]

Restricting access to needed anti-depressant or anti-psychotic medications could have an adverse effect on the ability of individuals with co-morbid medical conditions to manage other conditions with which they live.

It is important to recognize that even minor delays in care can have dire consequences for people diagnosed with serious mental illness. At a time when national attention is being focused on how best to address glaring problems with the mental health system, the imposition of potential limits on accessing needed anti-depressant and anti-psychotic medications would be ill-advised.

Equally concerning is CMS' promotion of the U.S. Department of Defense (DoD) and Veterans Administration (VA) formularies as adequate to ensuring patients' access to necessary medications.[52] 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 deplored.

The goal of prescription therapies for people living with serious mental illness is to sustain good health and prevent declines that warrant costly acute or emergency care. The current protected classes policy is consistent with this goal. Rolling back these protections would potentially interfere with achieving good treatment outcomes in unverified hopes that fallback protections will succeed in avoiding catastrophic outcomes.

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

[47] 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).

[48] 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.
[49] 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.
[50] 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.
[51] 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.
[53] 79 Fed. Reg. at 1942.

B. The Second Prong of the New Standard does not adequately take into consideration differential effects of specific anti-depressant and anti-psychotic medications on people with complex mental illnesses.

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

The second prong would appear to disregard the stated intent of Congress, as set forth in Section 3307, that CMS should develop a standard to strengthen existing patient protections. This second 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.*[53]

The intent of this standard appears to be to institute alternative policies to "limit the number of categories or classes of clinical concern receiving additional protections under the [ACA]."[54] This was not the intent of Congress in enacting Section 3307.

2. Research Documents that Psychiatric Medications are not Interchangeable

Individuals benefiting from the protected classes policy require access to a broader variety of drugs than individuals 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."[55]

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.[56]

The National Institute of Mental Health (NIMH) 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.[57] According to one of the STAR*D researchers, the study provides important information that intolerance or lack of efficacy with one SSRI antidepressant does not seem to predict the same with another.[58]

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[53] 79 Fed. Reg. at 1942.
[54] Ibid.
[55] 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.
[56] http://www.nami.org/Template.cfm?Section=Access_to_Medications&Template=/ContentManagement/ContentDisplay.cfm&ContentID=47683
[57] 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.
[58] 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.

Perhaps the most definitive explanation of the variable effects of specific psychiatric medications comes from the American Psychiatric Association (APA), whose guidelines CMS cites to justify undermining the protected classes policy for these patients.[59] In a letter recently submitted to CMS concerning the proposed rule, the APA states concisely: "CMS misrepresents APA's relevant practice guidelines" and further notes 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."

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

1. Appeals Procedures are Particularly Difficult to Utilize for People with Mental Illness

In NAMI's view, CMS errs in assuming that the *intended* regulatory timeframe for coverage determination and appeals processes provide adequate safeguards. First of all, there is strong reason to believe existing appeals processes are inadequate to ensure meaningful protections for vulnerable individuals with mental illness, much less within the timeframe CMS presumes. No data is provided suggesting that the exceptions process works.

In a September 12, 2013, presentation, MedPAC staff identified significant problems with Part D exceptions and appeals processes.[60] 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."[61]

[59] American Psychiatric Association, Letter to leaders of the House Energy & Commerce Committee (Feb. 25, 2014).
[60] 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.
[61] Ibid.

NAMI respectfully submits 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…"[62] As recently as last October, the OIG in assessing volume, outcomes, and timeliness of the first level of the Medicare appeals process reflected on its longstanding concerns.[63] 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.[64]

The current backlog in the appeals system does not even take into account the inevitable increase in appeals that would occur were CMS' proposal to restrict access to medically necessary medications under this proposed regulation to be implemented.

Revisiting CMS' guidance to plan sponsors upon originally implementing the protected classes, the agency asked, "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."[65] There is no evidence to suggest that this assertion is no longer true.

2. Additional Fallback Protections in Medicare are not Sufficient for People Living with Mental Illness

The additional Part D protections cited in the Proposed Rule are not adequate to justify limiting access to anti-depressant and anti-psychotic medications. [66] 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 evidence to support that these protections have ever been deemed sufficient by any policymaker to ensure the safety and quality of care for persons impacted by the six protected classes policy.

Furthermore, 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 living 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.[67] In comparison, the existing protected classes policy entitles Medicare beneficiaries to access to 57 medications: 23 generic antidepressants, 7 branded antidepressants, 18 generic antipsychotics

[62] https://oig.hhs.gov/oei/reports/oei-04-01-00290.pdf (emphasis added)
[63] https://oig.hhs.gov/oei/reports/oei-01-12-00150.pdf
[64] https://oig.hhs.gov/oei/reports/oei-02-10-00340.pdf
[65] 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.
[66] 79 Fed. Reg. at 1938-1941.
[67] Ibid.

and 9 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.

Close scrutiny of the protections set forth in the proposed rule show that they are plainly insufficient to meet the needs of these populations. For example, the proposed rule cites the "discrimination review" policy but notes it only is invoked to ensure coverage of "categories and classes used to treat all disease states."[68] 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.

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

We strongly urge CMS to take no further steps to potentially limit patient care by introducing new exceptions to whatever protections remain. CMS itself acknowledges that prior authorization for new starts will delay access to initial therapy, in conflict with the first prong of the weakened standard the agency proposes. But CMS simply endorses this component, citing the need of Part D plans to have yet another tool to cut costs.[69]

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

NAMI is also concerned about CMS' reference that it may use the annual Call Letter cycle to change the classes of clinical concern. The Call Letter cycle unquestionably fails to provide stakeholders sufficient time to react and respond to changes or restrictions that may be imposed. The approximately 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."[70] It is impossible for CMS to collect, review and react to comments on such a complicated and sensitive matter as removing these fundamental protections for vulnerable Medicare beneficiaries.

Conclusion

NAMI appreciates this opportunity to respond to CMS' Proposed Rule and the agency's consideration of the concerns we raise here with respect to the proposed changes to the Classes of Clinical Concern. We strongly believe that CMS has fundamentally misinterpreted the intent of Section 3307, which was to *protect* patients in areas of clinical concern.

The protections contained in the Medicare Part D program have been a lifeline for beneficiaries living with serious mental illness. One person wrote to us that "I dread the thought of having to go through trials of different bipolar drugs if the special protections are lifted and my necessary … medications are not offered. … I fear the adverse effects of trying what is offered, but equally the lack of control of my bipolar disorder if and until stabilized."

[68] 79 Fed. Reg. at 1939.
[69] 79 Fed. Reg. at 1944.
[70] Social Security Act § 1860D-4(b)(3)(G)(iii) (42 U.S.C. § 1395w-104(b)(3)(G)(iii)).

The criteria established in the proposed process are vague and contrary to broadly accepted clinical standards. They would potentially place vulnerable individuals in great jeopardy. **NAMI urges CMS to rescind these components of the Proposed Rule in their entirety and to implement Section 3307 in a manner that, at a minimum, guarantees the same degree of protection present before the Proposed Rule was issued.**

Other Provisions in the Proposed Rule

Given the significant harm to the interests of beneficiaries living with serious mental illness that would result from full implementation of the protected classes policy, NAMI is recommending that CMS pull back the entire rule. At the same time, NAMI would like to offer the following comments on other provisions in the Proposed Rule. In so doing, we emphasize that these provisions in no way offer a counterbalance to the negative impact of the changes CMS is seeking to the protected classes rule.

I. Proposed Expansion of the Medication Therapy Management ("MTM") Program

NAMI supports implementation of strategies that have a positive impact on the proper management of chronic conditions such as serious mental illness. These strategies can have a very positive impact on patient care and quality of life. Medication adherence is a substantial component of proper management of many chronic conditions and debilitating illnesses.

NAMI has long supported CMS' efforts aimed at incentivizing health care providers and health plans – whether under Medicare, the Medicaid program or under Qualified Health Plans offered through the Health Insurance Marketplace– to dedicate resources to the effective management of chronic conditions, especially in the case of serious mental illness accompanied by co-morbid physical conditions such as diabetes, heart disease, asthma and COPD.

The Proposed Rule would expand the medication treatment management (MTM) from the current requirement that recipients suffer from four (4) or more chronic conditions and take three (3) or more drug therapies to recipients with two (2) or more chronic conditions taking two (2) or more drug therapies. NAMI strongly supports this proposal, which according to the Pharmaceutical Care Management Association would expand MTM requirements from 8 percent of the Medicare population to 55 percent. MTM programs have demonstrated some successes in more effectively coordinating care among multiple prescribers treating patients with diverse and complicated co-morbid conditions.

However, NAMI believes that additional work is needed to validate standards of practice, credentialing and other evidence-based protocols to ensure that we know more about what are the effective attributes of successful MTM programs. What are the agreed upon outcomes that MTM programs should achieve? How will CMS measure fidelity to evidence-based practice with respect to MTM programs? NAMI recommends that CMS continue efforts to work with National Committee for Quality Assurance (NCQA), Pharmacy Quality Alliance (PQA) and National Quality Forum (NQF) and other accrediting bodies to evaluate MTM programs and develop more rigorous standards for MTM.

II. Proposed Inclusion of Quality of Care Requirements in Sponsor Contracts with CMS

In the Proposed Rule, CMS is proposing to require that all Medicare Part D plan sponsors contractually agree to provide "good quality health care" to their enrollees. CMS plans to define "good quality health care" by the achievement of three or more stars for performance measures in the following five categories under the Star Ratings Program—(1) patient outcomes; (2) intermediate outcomes; (3) patient experience;

(4) patient access to care; and (5) process. NAMI has long advocated for quality health care on behalf of beneficiaries living with mental illness, and we support this proposal and commend CMS for further evidencing its commitment to quality health care through its proposal. However, we caution CMS that there is a need to balance quality with patient access to affordable health care. As such, we believe CMS should afford Medicare Part D plan sponsors an opportunity to cure poor quality health care within a reasonable and specified time frame, as evidenced by a failure to achieve three (3) or more stars on certain performance measures, prior to terminating sponsor agreements with CMS. It will also be important for CMS to avoid additional disruption for vulnerable beneficiaries enrolled in these plans, particularly dual eligible and Low-Income Subsidy (LIS) beneficiaries.

Many of the plans that fail to consistently achieve the minimum three star rating are below their local regional benchmark standard and thus have disproportionate enrollment of LIS and dual eligible beneficiaries. Over the short-term, NAMI believes that the solution is to work with these plans to improve performance. Thus there should be flexibility in the rule to allow vulnerable beneficiaries to remain in these programs during the process of improvement as long as there is measurable progress and quality concerns are not placing people at serious risk.

III. Proposed Transparency in Pricing for Generic Drugs

CMS is proposing an update to the definition of "prescription drug pricing standard" to include Maximum Allowable Cost (MAC) prices and methodologies. As such, Medicare Part D plan sponsors will be required to update MAC prices at least weekly and make such prices available to consumers and pharmacies in advance of reimbursement. NAMI has long been an advocate for full pricing transparency. Beneficiaries should be able to learn via the Medicare Part D plan finder tool or otherwise their precise cost-sharing obligations at a given pharmacy for a given drug prior to arriving at the pharmacy to pick up a prescription. Generic drugs subject to a MAC by a Medicare Part D plan sponsor or pharmacy benefit manager should not be held to a different standard than brand and single-source generic drugs which are not typically reimbursed on a MAC basis. NAMI supports extending pricing transparency to all Part D drugs, regardless of the basis for reimbursement.

IV. Limiting Multiple Bids by Part D Plan Sponsors

Beginning in 2016, CMS is seeking to restrict Part D plan sponsors to two plan options per Medicare region – one "enhanced" plan and one "basic" plan, with the potential to go down to a single bid in in each region in future years. NAMI is extremely concerned about the potential impact of this proposal on the plan choices available to dual eligible and LIS beneficiaries. Under Part D rules, LIS and dual eligible beneficiaries can only enroll in "basic" plans that are at or below the regional benchmark level (in order to maintain the important beneficiary protection of a $0 monthly premium).

In recent years, CMS has been limiting the ability of plan sponsors to offer multiple bids within each region for "enhanced" and "basic" plan options. This is especially the case for "basic" plan options available for LIS and dual eligible beneficiaries since 2011. The result has been a continued diminishment of plan options for LIS and dual eligible beneficiaries – a population in which beneficiaries with mental illness are disproportionately represented. According to the Kaiser Family Foundation, the number of free-standing Prescription Drug Plans (PDPs) at or below the regional benchmark has steadily declined in recent years. In 2007, there were 640 PDPs below the regional benchmark and available to LIS and dual eligibles at a $0 monthly premium. By 2013, that number had declined to 331 PDPs.

During this period CMS has already been limiting multiple bids by Part D plan sponsors. This proposed rule seeks to further limit the number of plan bids and is likely to further restrict plan choice for poorest and most vulnerable beneficiaries. It is important to note that these "basic" plan options vary from year to

year and that many LIS and dual eligible beneficiaries are often subject to "auto reassignment" as the plan they are enrolled in moves above the regional benchmark – essentially, involuntary disenrollment and reassignment to a different plan. NAMI is concerned that this proposal to further limit plan sponsor bids will lead to more limited plan options for LIS and dual eligible beneficiaries and risk a higher volume of "auto reassignments" in future years. At minimum, it is likely to continue to trap low-income beneficiaries in a limited number of PDP offerings.

As MedPac recently recommended in a letter to CMS on this proposed rule,

> "Given these uncertainties and the short time frame between when the rule is finalized and when plan sponsors must submit their bids for the 2015 benefit year, we strongly encourage CMS to delay making this change for 2015. In the meantime, we encourage CMS to use its authority to reject plan bids that discriminate against certain groups of beneficiaries based on LIS status and/or health status."

NAMI urges CMS to reconsider the current cap on multiple "basic" plan option bids and work to ensure that there are a sufficient number of plan options below benchmark for LIS and dual eligible beneficiaries.

Thank you for affording us this opportunity to comment.

Mary Giliberti, J.D.
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