American Autoimmune Related Diseases Association, Inc.

www.aarda.org

January 25, 2019

By Electronic Submission to http://www.regulations.gov

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4180–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Proposed Rule Comments—Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS–4180–P)

Dear Administrator Verma:

The American Autoimmune Related Diseases Association, Inc. (AARDA) and additional undersigned patient advocacy organizations appreciate the opportunity to comment on the Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS) proposed rule titled *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses* ("proposed rule").[1] Among other comments, we write, in particular, to express concerns regarding proposed changes that would significantly erode the important and longstanding protections under Medicare Part D that apply to therapies in six categories identified as "classes of clinical concern,"[2] and that would permit Medicare Advantage (MA) plans to apply step therapy requirements to Part B drugs.

We are concerned that these proposed changes, if finalized, would impose severe restrictions on medication access that would harm beneficiaries, undermine important statutory requirements, and fail to advance CMS' stated cost-containment objectives. For individuals with serious and complex diseases, including autoimmune diseases, reliable access to prescription therapies very often is critical to appropriately treating and managing their conditions. Policies that restrict or prevent such access can lead to poor clinical outcomes, deteriorating conditions, costly hospital visits, and other negative consequences that not only threaten patients' health and well-being, but also lead to increased healthcare expenditures and other costs.

AARDA is dedicated to the eradication of autoimmune diseases and the alleviation of suffering and the socioeconomic impact of autoimmunity. AARDA is the only national nonprofit organization dedicated to bringing a national focus to autoimmunity, a major cause of serious and chronic diseases. Approximately 50 million Americans, 20 percent of the population or one in five people, suffer from one or more autoimmune diseases. AARDA is also the founder and facilitator of the National Coalition of Autoimmune Patient Groups (NCAPG), a coalition of 38 patient advocate organizations, representing numerous autoimmune diseases. The mission of the NCAPG is to consolidate the voice of autoimmune disease patients and to promote increased education, awareness, and research into all aspects of autoimmune diseases through a collaborative approach.

[1] 83 Fed. Reg. 62,152 (Nov. 30, 2018).
[2] *See* Medicare Prescription Drug Benefit Manual, CMS Pub. 100-18, Ch. 6, § 30.2.5.

Individuals with autoimmune diseases face significant health challenges, often requiring lengthy processes with physicians and therapeutic trial-and-error in order to diagnose, treat, and manage their symptoms. All autoimmune disorders share a common feature—the body's immune system attacks itself—yet this group of more than 100 chronic diseases spans a multitude of diverse conditions.

Even within each disease state, patients with the same disorder experience varied symptoms and, as a result, react differently to different treatments: what works for one lupus patient, or rheumatoid arthritis patient, or Sjögren's syndrome patient, for example, often will not work for another patient with the same disease.[3] For many patients with autoimmune diseases, medications within the six classes of clinical concern are an important treatment option. Access to the full range of these medicines is critically important in light of patients' individualized manifestations of autoimmunity and varied immune reactions and responses to different treatments. A number of patients with autoimmune diseases also have multiple autoimmune diseases and/or other conditions, thus adding further complexity to disease treatment and management.

In addition to facilitating and helping to maintain patients' health and well-being, appropriate and effective management of chronic conditions through prescription drugs also helps to contain healthcare system costs by preventing hospitalizations, reducing the frequency and impact of relapses, and protecting against declining conditions that can lead to disability and other negative outcomes. For these and other reasons, as discussed in further detail below, CMS should not finalize its proposed exceptions and other changes to the longstanding Part D protected classes policy and, instead, should retain the policy's existing protections that help ensure appropriate access and nondiscrimination—as required by statute—for patients with serious and chronic conditions. We also urge CMS to reconsider its proposal to permit MA plans to apply step therapy requirements for Part B drugs under certain conditions; we are concerned that this proposal risks significant harm to beneficiaries and is not consistent with applicable statutory provisions.

I. CMS Should Not Finalize Its Proposed Changes to the Protected Classes Policy

AARDA has serious concerns about the proposed changes and exceptions to the longstanding access protections that have applied since the Part D program's inception for therapies in the six identified classes of clinical concern—specifically, the antidepressant, antipsychotic, antineoplastic, immunosuppressant, anticonvulsant, and antiretroviral categories. Under this protected classes policy, plans have been required since Part D's initial implementation on January 1, 2016, to include on plan formularies "all or substantially all" of the drugs in the six protected classes. We are concerned that the current proposals, if finalized, would create unnecessary access barriers and lead to harmful formulary exclusions, increased use of prior authorization requirements, and proliferation of step therapy protocols that would threaten patients' ability to receive appropriate care.

CMS has expressly recognized since 2005 that the six protected classes policy is necessary to address the clinical needs of patients with complex conditions, and to fulfill the Part D statute's

[3] *See, e.g.*, Mayo Clinic, *Lupus: Symptoms & Causes* (Oct. 25, 2017), *available at* https://www.mayoclinic.org/diseases-conditions/lupus/symptoms-causes/syc-20365789 (noting that "[n]o two cases of lupus are exactly alike," and that "symptoms vary considerably from person to person"); National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), *Health Topics: Rheumatoid Arthritis* (Apr. 30, 2017), *available at* https://www.niams.nih.gov/health-topics/rheumatoid-arthritis/advanced#tab-treatment (describing various treatments for rheumatoid arthritis and how they may vary from person to person, and noting the importance of using "drug combinations instead of one medication alone"); American College of Rheumatology, *Sjögren's Syndrome* (Mar. 2017), *available at* https://www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Sjogrens-Syndrome (noting that "[s]ymptoms vary in type and intensity" and describing several types of treatments that may work in "some" patients but not others, depending on the patient's specific characteristics and symptoms).

nondiscrimination requirements.[4] In implementing the policy, CMS also recognized "that interruption of therapy in these categories could cause significant negative outcomes to beneficiaries in a short timeframe."[5] CMS further noted that the agency's "requirements for these six categories of drugs are consistent with our review of commonly-used formularies."[6] The Medicare Part D Manual likewise has long reflected—and today continues to reflect—this policy and the necessity of these requirements in order to protect against discrimination and "to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[7]

Consistent with these statements from CMS in support of the six protected classes policy, any disruption of access to healthcare services, including access to the full range of appropriate medications within these identified classes of clinical concern, can be devastating—even life-threatening—to patients, and also risks undermining or even violating the Part D statute's nondiscrimination and beneficiary access protections. Congress likewise has recognized the importance of these protections and the clinical realities that render them so critical. Indeed, Congress has codified these protections in statute, and it has expressly acknowledged that the policy applicable to "these six drug classes is based on the reality that the medications in these categories are ***not clinically interchangeable*** and that a limit in formularies of only two drugs ***would pose a dangerous risk to the most vulnerable and medically fragile of Medicare beneficiaries***."[8]

As CMS, Congress, and others have long recognized, the medicines included in the classes of clinical concern are not interchangeable, and, accordingly, it is important for purposes of the Part D statute's nondiscrimination provisions that plans provide access to "all or substantially all" drugs within each of these classes. Since the initial implementation of the Part D program, protections have been in place to help ensure appropriate access to therapies in the six identified classes of clinical concern. These protections are well-established and are no less relevant or imperative today than they were at the time of Part D's inception. Medicare Part D's statutory nondiscrimination requirements—the basis for the "six protected classes" policy—have not changed, nor has the "clinical reality" that the medications in these categories are not interchangeable. Further, the existing six protected classes policy has now been codified in statute for nearly a decade. As discussed in more detail below, the proposed changes to this important policy should not be finalized, as we fear they would harm beneficiaries, undermine the statute's nondiscrimination mandate, and fail to meaningfully reduce drug prices, overall healthcare spending, or patients' out-of-pocket costs.

A. History and Importance of the Existing Protected Classes Policy

In the proposed rule's "History of the Protected Class Policy" section, CMS acknowledges that, even before Medicare Part D took effect, CMS recognized the need to direct plans to "include on their formularies all or substantially all drugs" in the six protected classes.[9] While AARDA agrees that CMS' guidance in

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[4] *See, e.g.*, CMS, *Final Medicare Modernization Act (MMA) Formulary Guidance Q&A* (2005), *available at* http://web.archive.org/web/20050917024627/http:/www.cms.hhs.gov/pdps/formularyqafinalmmrevised.pdf. In this guidance, CMS addressed the question "Why is CMS requiring 'all or substantially all' of the drugs in the antidepressant, antipsychotic, anticonvulsant, immunosuppressant and HIV/AIDS categories?" by stating, among other points, as follows: "CMS has a responsibility under the Medicare Modernization Act (MMA) to make sure beneficiaries receive clinically appropriate medications so that formularies are not discriminatory. In our final formulary guidance for 2006, we noted that a majority of drugs in these categories would have to be on plan formularies and that beneficiaries should have uninterrupted access to all drugs in that class." *Id.*

[5] *Id.*

[6] *Id.*

[7] *Medicare Prescription Drug Benefit Manual*, CMS Pub. 100-18, Ch. 6, § 30.2.5 (setting forth the protected classes policy requirements and explaining that CMS instituted these requirements "because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations").

[8] 153 Cong. Rec. H469 (Jan. 12, 2007) (emphases added).

[9] *See* 83 Fed. Reg. at 62,155.

2005 and 2006 helped to ensure a smooth transition of the Medicare-Medicaid dual eligible population to the Part D program, we disagree with CMS' implication in the proposed rule that current circumstances are sufficiently different to support the proposed erosion of the existing and longstanding protections under the six protected classes policy.

First, the clinical concerns and discrimination risk that fueled the initial implementation of the six protected classes policy remain fully applicable and relevant today. With respect to the patients with autoimmune diseases, data and experience demonstrate that patient responses to different therapies vary greatly, and, as a result, the available medicines often are not interchangeable for particular patients and their specific experiences with autoimmunity.[10] Given the complex, chronic, and often incurable nature of autoimmune diseases, as well as how they interact with other conditions that a patient might have, access to the full range of available—and non-interchangeable—treatments within the protected classes is essential.

Moreover, the clinical value of ensuring health care providers' flexibility to prescribe, and patients' ability to receive, different options is underscored by the impact of co-morbidities in this patient population. As noted above, many patients with autoimmune disorders have multiple conditions and symptoms that require treatment with numerous medicines, often in several classes.[11] Having access to only a truncated selection of the available options or imposing additional obstacles to accessing certain therapies would risk treatment delays and disruptions and may fail to appropriately manage the myriad potential interactions among a patient's different medications and conditions.

In addition to the clinical rationale and nondiscrimination imperative supporting the existing protected classes policy, this policy also has enjoyed bipartisan support from Congress since its inception, including statutory enactments in 2007 and 2010, as well as other supportive statements and communications. Emblematic of this sustained bipartisan support, when CMS last proposed restrictive changes to the six protected class policy in 2014, the full Senate Finance Committee submitted a letter to CMS expressing concerns about the proposed changes and urging CMS to retain the existing policy.[12] As both Congress and CMS have recognized, the existing protected classes policy is consistent with important clinical realities and statutory requirements. Accordingly, we urge CMS to maintain—and not disrupt—this successful policy and the protections that it provides for patients with serious and chronic conditions.

B. Concerns Regarding the Proposed Expansion of Utilization Management Tools and Proposed Indication-Specific Protections

We are concerned about threats to patient access that we fear would result if CMS were to finalize its proposal to permit expanded utilization management tools for drugs in the current protected classes, including for patients already stabilized on a therapy. Utilization management can come in many forms,

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[10] *See, e.g.*, Kanako Kitahara & Shinichi Kawaib, *Clyclosporine and Tacrolimus for the Treatment of Rheumatoid Arthritis*, Current Opinion in Rheumatology 19(3):238-45 (2007); Matthias Weiwad, *et al*., *Comparative Analysis of Calcineurin Inhibition by Complexes of Immunosuppressive Drugs with Human FK506 Binding Proteins*, Biochemistry 45(51): 15776-84 (2006).

[11] *See, e.g.*, NIH, *Progress in Autoimmune Diseases Research*, at i (Mar. 2005) (noting that "overlapping genetic traits enhance susceptibility to many of the diseases, so that a patient may suffer from more than one autoimmune disorder"); *id.* at 55 (noting that treatments for autoimmune patients include medications to replace or repair areas of impaired functioning as well as immunosuppressants to suppress the body's destructive autoimmune response); Mayo Clinic Staff, *Antidepressants: Another Weapon Against Chronic Pain* (Sept. 13, 2016), *available at* http://www.mayoclinic.org/pain-medications/art-20045647 ("[A]ntidepressants are a mainstay in the treatment of many chronic pain conditions, even when depression isn't recognized as a factor").

[12] Letter from United States Senate, Committee on Finance, to Marilyn Tavenner, Administrator, CMS (Feb. 5, 2014). Fifty bipartisan Members of the House Ways & Means and House Energy & Commerce Committees signed a similar letter to HHS/CMS, dated March 4, 2014, urging that the proposed changes to the six protected classes not be finalized.

such as prior authorization and step therapy. If implemented, the proposed changes would jeopardize efforts to ensure that Medicare beneficiaries living with autoimmune and other serious diseases receive the clinically appropriate treatment that they and their physicians understand is best for them. Under the proposal, CMS would allow Part D plans to increase their use of prior authorization and step therapy requirements—policies that often are harmful to patients by causing therapy delays and disruptions. These tools, and step therapy, in particular, disrupt the physician-patient relationship and can cause significant negative consequences for individuals with autoimmune and other diseases in light of their varying responses to different treatments.

We also are concerned that, for individuals with autoimmune diseases and other serious and chronic conditions, purported cost-saving measures that are premised upon access restrictions would, if implemented, lead to increased medical spending, not reduced costs. In the face of ample data evidencing the importance of maintenance therapy and continuity of care in avoiding hospitalizations and relapses,[13] subjecting patients who are stabilized on a drug to prior authorization, step therapy, or other utilization management requirements risks serious consequences for patient health. It also undermines cost-containment goals in light of the very high costs of hospitalizations and other clinical interventions and consequences that occur when patients' chronic conditions are not effectively managed.[14] Indeed, data and studies have shown that appropriate access to medications under Medicare Part D reduces, not raises, medical spending.[15]

Further, efforts to "switch" patients to different medications that are or may appear to be lower in cost, but that are not necessarily clinically appropriate or optimal for the patient, can carry direct clinical risk. For example, abrupt loss of access to a therapy—particularly for patients with serious and chronic conditions that may be at risk for relapse—can threaten patients' long-term prognosis and recovery potential.[16] Similarly, patients with autoimmune diseases and other conditions may have immune sensitivities to active or inactive ingredients in certain medications, such that a "switch" to another therapy, even if in the same category or class, may lead to adverse events, reduced efficacy, or other negative consequences.

We are concerned, as well, about the proposed rule's suggestion that CMS may consider attempting to limit the access protections for therapies in the classes of clinical concern to specific indications—and to allow increased access restrictions with respect to "medically-accepted indications for non-protected class uses."[17] As recognized by CMS, "medically-accepted indications" are those that are "approved by the Food and Drug Administration (FDA) or [that are] supported by one or more citations included or approved for inclusion in specified compendia." Such uses are well-established, well-supported, and covered by the Part D program. The potential exclusion of such uses from the protections applicable to therapies within the classes of clinical concern is alarming from a clinical perspective and from the standpoint of preventing discrimination against beneficiaries based on their health status or condition. Therapies within the protected classes are not clinically interchangeable—and that reality does not depend upon the particular indications

[13] *See, e.g.*, Stephan Kanzler et al., *Duration of Immunosuppressive Therapy in Autoimmune Hepatitis*, J. Hepatology, 34:354–355 (2001) (describing the importance of immunosuppressive therapy to sustained remission and prevention of relapse in patients with autoimmune hepatitis); Christopher C. Afendulis et al., *The Impact of Medicare Part D on Hospitalization Rates*, Health Servs. Res., 46(4):1022–38 (2011) (finding that implementation of Part D reduced hospitalization rates).
[14] *See, e.g.*, John Hsu et al., *Unintended Consequences of Caps on Medicare Drug Benefits*, NEJM, 354(22):2349–59 (2006) (finding that Medicare+ Choice beneficiaries with a capped drug benefit had higher relative rates of ER visits, non-elective hospitalizations, and death, compared to those with unlimited drug coverage).
[15] *See, e.g.*, Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (Nov. 2012); J. Michael McWilliamset et al., *Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage*, JAMA, 306(4):402–409 (2011) (finding that Medicare beneficiaries' increased access to and use of prescription drugs through expanded coverage under Part D was linked to reduced non-drug medical spending).
[16] *See, e.g.*, David P. Richman & Mark A. Agius, *Treatment of Autoimmune Myasthenia Gravis*, Neurology, 61:1652–1661 (2003); Stephan Kanzler et al., *Duration of Immunosuppressive Therapy in Autoimmune Hepatitis*, J. Hepatology, 34:354–355 (2001).
[17] 83 Fed. Reg. at 62,158.

for which a therapy may be prescribed. Moreover, a number of patients, as noted, have multiple diseases and may rely on multiple therapies. Access limitations based on purported "protected" vs. "non-protected" uses would be divorced from the clinical realities that exist for patients with complex and chronic conditions—the very patients whom the protected classes policy is in place to protect. Such limitations also would add unnecessary and undue administrative burdens for plans, providers, patients, and CMS. We strongly urge the agency to abandon this unnecessary and potentially discriminatory restriction on the protections applicable to therapies that are within the categories of clinical concern.

C. Concerns About CMS' Asserted Rationale for the Proposed Changes

Although CMS asserts in the proposed rule that requiring "essentially open coverage"[18] of certain drug classes can lead to overutilization and increased costs to the Part D program, the proposed rule fails to recognize the data and evidence showing the significant savings across the healthcare system that can result from appropriate and effective use of prescription drugs. For example, a November 2012 Congressional Budget Office report concluded, based on several studies, that increases in prescription drug use by Medicare beneficiaries leads to offsetting reductions in Medicare's spending on medical services.[19] Additional studies similarly have found that Medicare beneficiaries' improved access to prescription drugs following the implementation of Part D has led to reduced hospitalization rates[20] and reduced non-drug medical spending.[21] Moreover, studies have found that patients with capped prescription drug benefits experience higher relative rates of emergency room visits, non-elective hospitalizations, and death, compared to those whose drug coverage is not capped.[22]

While AARDA agrees that cost containment is an important goal, we are concerned that the proposed changes and restrictions for the existing protected classes policy under the proposed rule would not, if finalized, lead to any meaningful reductions in medical spending or patient out-of-pocket costs. Indeed, the proposed changes, if finalized, likely would increase out-of-pocket costs for patients with serious and chronic conditions who may face formulary restrictions or utilization management barriers affecting their access to the medications prescribed by their physicians. Such individuals also would likely experience negative clinical consequences, which, as a result, also could lead to increased healthcare system costs.

D. Limiting Beneficiary Access and Options Runs Counter to Part D's Nondiscrimination Mandate and to Principles of Patient-Centered Care

The clinical needs of vulnerable patient populations and the nondiscrimination mandate of the Part D statute formed the foundation for implementing the protected classes policy at the start of the Part D program and for maintaining it ever since, including memorializing these important protections in statutory provisions, regulations, and guidance. These protections remain as critically important to patients today as they were at the start of the Part D program. We are concerned that, in proposing changes to the protected classes policy under the proposed rule, CMS has not undertaken an analysis of the potential for discrimination against individuals who rely on therapies in the protected classes.

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[18] 83 Fed. Reg. at 62,156.
[19] Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (Nov. 2012).
[20] *See, e.g.*, Christopher C. Afendulis et al., *The Impact of Medicare Part D on Hospitalization Rates*, Health Servs. Res., 46(4):1022–38 (2011) (finding that implementation of Part D reduced hospitalization rates).
[21] *See, e.g.*, J. Michael McWilliams et al., *Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage*, JAMA, 306(4):402–409 (2011) (finding that Medicare beneficiaries' increased access to and use of prescription drugs through expanded coverage under Part D was linked to reduced non-drug medical spending).
[22] *See, e.g.*, John Hsu et al., *Unintended Consequences of Caps on Medicare Drug Benefits*, NEJM, 354(22):2349–59 (2006).

The proposed rule appears to mention the law's protection against discrimination by plans only once, as a point of reference in the "History of the Protected Class Policy" section.[23] Rather than focusing on patients' clinical needs and the statutory nondiscrimination requirements, the proposed rule instead appears to focus on an asserted need to provide greater flexibility for plans to impose access restrictions and tighten formulary coverage. Yet plans already have numerous tools at their disposal, including formulary tiering and prior authorization requirements, which they apply to therapies in the protected classes. We are concerned that the proposed rule does not reflect an appropriate balance between the desire for increased plan flexibility and the law's nondiscrimination and beneficiary access requirements.

Under the Part D statute, the Secretary must not approve a plan with a benefit design, "including any formulary and tiered formulary structure," that would be "likely to substantially discourage enrollment by certain part D eligible individuals under the plan."[24] Access to medications as prescribed by their physicians is paramount for patients with complex conditions. And a lack of such access, or significant barriers to such access, can have the effect of "substantially discouraging enrollment by certain part D eligible individuals under the plan." As such, policies that allow plans to eliminate patients' therapeutic options and further restrict access to medically appropriate care are not only contrary to important clinical considerations and principles of patient-centered care, but they also undermine and may violate the statute's nondiscrimination imperative by discouraging certain beneficiaries' enrollment in such plans. Accordingly, CMS should retain the existing protections for therapies included in the protected classes, which help to ensure an appropriate balance between plan flexibility and patient-centered clinical needs and nondiscrimination requirements.

II. Concerns with Changes Permitting Use of Step Therapy for Part B Drugs Under MA Plans

We are deeply concerned that CMS has proposed to allow MA plans to use step therapy for Part B drugs under certain conditions. Previously, CMS interpreted existing law to prohibit MA plans from using step therapy for Part B drugs. Under a significant change announced by CMS in August 2018 and reflected in the proposed rule, however, beneficiaries enrolled in MA plans may face risks, starting in contract year 2019, of potential negative effects from step therapy programs for Part B drugs. As noted, CMS first announced this position change in a guidance document issued in August 2018.[25] Under the proposed rule, CMS has proposed regulatory provisions to implement this change. We believe the policy reflected in the proposed rule would run contrary to the clinical needs of patients and, moreover, may be inconsistent with the underlying statute. Accordingly, we urge CMS to reverse this recent change in its position and to reinstitute its prior guidance that expressly prohibited step therapy requirements for Part B drugs.

Since 2012 (up until the position change announced in August 2018), CMS guidance has explicitly prohibited mandatory step therapy for Part B drugs, while allowing other utilization management tools.[26] As CMS recognizes in the proposed rule, the agency's prior guidance[27] "***interpreted existing law to prohibit*** MA plans from using step therapy for Part B drugs."[28] We believe that the interpretation reflected in CMS' prior guidance was—and is still—correct. We further agree with the prior guidance's recognition that the use of step therapy when applied to Part B drugs "would create an unreasonable barrier to coverage of and

[23] *See* 83 Fed. Reg. at 62,155.
[24] *See* SSA § 1860D–11(e)(2)(D)(i) (nondiscrimination requirements for Part D plan and benefit design, "including any formulary and tiered formulary structure," requiring that such design must not be "likely to substantially discourage enrollment by certain part D eligible individuals under the plan").
[25] CMS, *Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage* (Aug. 7, 2018), *available at* https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.
[26] CMS, *Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services* (Sept. 17, 2012).
[27] *Id*.
[28] 83 Fed. Reg. at 62,169 (emphasis added).

access to Part B benefits that MA plans must provide under the law."[29] These requirements under the law cannot be jettisoned simply to provide MA plans with increased flexibility to further manage their costs. Plans already have multiple tools that they can, and do, use to manage costs, including formulary tiering, cost-sharing structures, and other utilization management techniques such as prior authorization. Step therapy protocols interfere with the physician-patient relationship, expose patients to treatment delays and disruptions, and add significant administrative burdens and clinical risks.

Just because a therapy may be viewed as appropriate for "most" patients, that does not mean it is an appropriate option for all patients. As noted above, patients with autoimmune diseases frequently experience significant variations in their different manifestations of their diseases and their reactions to different treatments. Moreover, autoimmune disease patients are particularly susceptible to even very minor changes in a drug, including, in many cases, differences in a product's inactive ingredients such as dyes or fillers. Patients' treatment physicians are best positioned to prescribe clinically appropriate therapies. Imposing step therapy policies that force patients to start on a treatment other than what their physician has prescribed can cause serious harm.

For these reasons, we urge CMS to reconsider the policy change announced in its August 2018 guidance and to refrain from finalizing the proposed changes that would allow MA plans to impose step therapy requirements for Part B drugs.

III. A Trend Toward Restricted Patient Access Is Not the Solution to Rising Healthcare Costs

We are concerned that the proposed changes to the protected classes policy and the proposal to permit MA plans to use step therapy for Part B drugs may be illustrative of an overarching trend toward policies that restrict, rather than facilitate, patient access to necessary and appropriate care. Although the stated rationale for these proposals relates to a desire to contain costs, we do not believe that restricted patient access is the solution to rising healthcare expenditures.

We encourage CMS to consider the impact of its policy proposals on patients, and to work with stakeholders to develop policies that promote patient access to clinically appropriate care, ensure protections against discrimination, and lower out-of-pocket costs. Restricting access is not a meaningful or appropriate mechanism for improving the affordability of necessary care for patients. As discussed above, a strong body of evidence shows that aggressive access restrictions, particularly for prescription drugs, often lead to costly hospitalizations, relapses, emergency room visits, and other negative clinical consequences that increase medical spending rather than containing it. Such consequences also lead to significant societal harm in the form of lost productivity or disability. For all of these reasons, we earnestly hope that CMS will reconsider and will not finalize its proposed changes to the protected classes policy or its proposal to permit step therapy for Part B drugs under MA plans, and that the agency will work together with stakeholders to explore and develop policy proposals that work for patients, providers, and plans alike.

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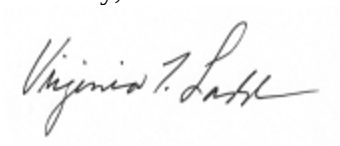
We share CMS' goals to improve patient outcomes, elevate the quality of care, contain healthcare system costs, and reduce patients' out-of-pocket expenditures. The best way to do this is to keep patients well and facilitate appropriate access to the care and treatments that they need. We urge CMS to support and advance policies that facilitate patients' access to the treatments and therapies that their physicians recommend, and that help avoid negative and costly outcomes such as deteriorating conditions, relapses, and repeated or extended hospitalizations and expensive acute care.

[29] 83 Fed. Reg. at 62,169 (discussing the September 2012 guidance).

Thank you for your consideration of our comments. We look forward to continuing to work with you on these important issues.

Sincerely,



Virginia T. Ladd
President/Executive Director, AARDA

On behalf of

American Autoimmune Related Diseases Association (AARDA)

American Behcet's Disease Association (ABDA)

Beyond Celiac

Celiac Disease Foundation

Digestive Disease National Coalition

Dystonia Medical Research Foundation

Dystonia Advocacy Network

GBS|CIDP Foundation International

International Pemphigus and Pemphigoid Foundation

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The Marfan Foundation

The Myositis Association

U.S. Hereditary Angioedema Association

Vasculitis Foundation

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