American Autoimmune Related Diseases Association, Inc.
www.aarda.org

By Electronic Submission

May 9, 2016

Mr. Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1670–P
P.O. Box 8016, Baltimore, MD 21244–8016

RE: Medicare Program; Part B Drug Payment Model Proposed Rule [CMS–1670–P]

Dear Acting Administrator Slavitt:

The American Autoimmune Related Diseases Association, Inc. (AARDA) and additional undersigned organizations appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Part B Drug Payment Model Proposed Rule (Proposed Rule).[1] AARDA is the only national nonprofit organization dedicated to raising awareness and addressing the problem of autoimmunity, which, as the second-leading cause of chronic disease in this country, affects more than 50 million Americans. AARDA is focused on eradicating autoimmune diseases and alleviating the suffering and socioeconomic impact of autoimmunity through fostering and facilitating collaboration in the areas of education, public awareness, research, and patient services.

AARDA is also the founder and facilitator of the National Coalition of Autoimmune Patient Groups (NCAPG), a coalition of 37 patient advocate organizations representing numerous autoimmune diseases, including lupus, psoriasis, rheumatoid arthritis, multiple sclerosis, relapsing polychondritis, Sjögren's syndrome, and many others. 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.

Individuals with autoimmune diseases face significant health challenges, often requiring a unique combination of drugs to diagnose, treat, and manage their symptoms. Prompt access to appropriate treatments, and to healthcare providers who can prescribe those treatments and follow patients' progress, is critical to autoimmune patients. On behalf of these individuals and their families, and in light of AARDA's deep commitment to ensuring meaningful access to appropriate care for patients with autoimmune diseases, we offer the following comments on the Proposed Rule.

I. Executive Summary

Although we appreciate the Agency's efforts to reduce Medicare expenditures for beneficiaries and for the federal government, we have serious concerns about the proposed Part B drug payment model and the impact that it would have—if finalized—on the program's sickest and most vulnerable patients. We share the concerns of numerous other patient advocate groups, community organizations,

[1] 81 Fed. Reg. 13,230 (Mar. 11, 2016).

Members of Congress, healthcare providers, provider groups, specialty societies, and other stakeholders that have urged CMS to withdraw this proposal. Before moving forward, CMS must propose and seek input on significant changes and must ensure more robust and meaningful protections for patients.

The striking breadth of the proposal and the compressed timeline being contemplated for its implementation raise extremely significant and utterly fundamental concerns from the perspective of patients' access to necessary therapies. For millions of patients who rely on prescription medications covered under Medicare Part B, including many with life-threatening or life-altering autoimmune disorders, cancers, immune deficiencies, and other diseases, there are very limited—and, in a number of cases, a complete lack of—alternatives available to treat their conditions. We are deeply concerned that the Proposed Rule fails to appreciate the role of these medicines in saving, sustaining, and improving lives—and, in doing so, saving and conserving precious resources that otherwise would be expended on hospitalizations, lost productivity, care for deteriorating conditions, and other costly and harmful consequences that result when serious and chronic conditions are not appropriately managed and treated. The Proposed Rule also fails to appreciate the limited number of treatments available for autoimmune disorders and the reality that, for many patients, less expensive alternative therapies simply do not exist.

The unintended consequences of this Proposed Rule, if implemented, will be to restrict patients' access to treatments that manage their conditions, forcing them to either forego therapy or to seek infusion treatments from more expensive and potentially less safe provider settings. These unintended consequences are all the more troubling in light of the Agency's proposal to start the demonstration, at the outset, on a nationwide scale. We do not believe it is appropriate to implement this "test" on such a broad basis without first exploring more fully its potential consequences and, only then, if the model is initiated, exploring its impact in a more limited manner as a first step. Indeed, the statute governing the CMS Center for Medicare and Medicaid Innovation (CMMI) itself states that models tested under CMMI's authority should "address[] a ***defined population***"[2] and should be expanded only if specific statutory conditions have been satisfied.[3] As proposed, the model begins far too broadly.

Below, we provide further detail on the policy, legal, and ethical concerns raised by the Proposed Rule. We strongly urge CMS to withdraw the proposed model. At the very least, CMS must suspend its finalization pending further review and consideration of the comments received. We join the chorus of stakeholders urging that significant changes must be made to the proposal—and, in particular, changes to ensure appropriate patient protections and access to needed medications—before proceeding. For many patients with serious and life-threatening disorders, these issues present literal matters of life and death. For others, they are the difference between being able to function and complete daily life activities—or not. We urge CMS to appreciate the magnitude of this proposal and its potential impact, and to give further consideration to these critically important issues.

II. Policy Concerns

We are tremendously concerned that the Proposed Rule, if finalized, would engender discrimination based on beneficiaries' health status or health conditions, and would foster perverse incentives resulting in patient access barriers and inappropriate rationing of care.

a. *Discrimination*

Chief among our concerns about the proposed model is that its impact will be to discriminate based on beneficiaries' health status or condition. First, for a number of autoimmune disorders, there

[2] Social Security Act (SSA) § 1115A(b)(2) (emphasis added).

[3] *See* SSA § 1115A(c) (addressing "Expansion of Models").

are very limited treatment options. Indeed, there is ***no*** FDA-approved therapy for several autoimmune conditions, such as Sjögren's syndrome and relapsing polychondritis, to name just two. For patients who have these disorders, many of which are rare diseases for which robust clinical trials are difficult if not impossible to conduct, the available treatments are not interchangeable, nor can patients find alternative solutions in other options (including "less expensive" alternatives that the Proposed Rule suggests may be available). To implement a payment model that actively discourages the use of these "higher cost" medicines under Part B is, quite literally, to actively discourage the ability for many patients with these conditions to have access to any treatments at all for their diseases. There are no other options to fall back on. The proposal fails to account for this reality, and the result will be discriminatory and devastating for vulnerable patients with limited treatment options, including many autoimmune patients.

Second, although CMS has proposed a carve-out for certain oncology drugs that are used consistent with an existing demonstration project, CMS has not proposed to carve out any other vulnerable patient population or demonstration project. Third, by targeting Medicare Part B patients with high drug costs, CMS is targeting high-cost patients who rely on frequent provider visits. These patients are predominantly patients with chronic diseases, such as our members.

Given this disproportionate effect on vulnerable patients—and, in particular, ones who have certain types of serious and chronic conditions with very limited treatment options—CMS is effectively imposing a model that discriminates against certain Medicare beneficiaries based on their health status. Under the proposed model, patients with chronic diseases, such as many autoimmune patients, would bear the greatest burden and would face access restrictions for many products, disruptions in treatment, and other severe discontinuities in care. These negative consequences are harmful to patients and costly to the healthcare system overall. They are also fundamentally inconsistent with statutory protections against discrimination in healthcare under the Medicare Act and the Affordable Care Act (ACA).

As CMS is well aware, Section 1557 of the ACA prohibits healthcare-based discrimination.[4] This provision, and others under the ACA[5] and Medicare Act,[6] underscore that it is unlawful to discriminate against or discourage enrollment of beneficiaries based on their health condition, health status, or disabilities. Proposed regulations to implement ACA Section 1557, promulgated by the Department of Health and Human Services (HHS) Office for Civil Rights (OCR), would apply "to any health program or activity, any part of which receives Federal financial assistance from any Federal agency," as well as "to all programs and activities that are administered by an Executive Agency or any entity established under Title I of the ACA."[7]

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[4] 42 U.S.C. 18116.

[5] *See, e.g.*, ACA § 1311(c)(1)(A) (prohibiting qualified health plans from "employ[ing] marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs"); 45 C.F.R. § 156.225(b) (same); 45 C.F.R. § 156.125 (providing that an insurance "issuer does not provide [essential health benefits] if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions").

[6] *See, e.g.*, SSA § 1860D-11(e)(2)(D)(i) (stating that a Medicare Part D plan cannot be approved unless the HHS Secretary "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan"); Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5; CMS, Final MMA Formulary Guidance Q&A (2005), *available at* http://web.archive.org/web/20050917024627/http:/www.cms.hhs.gov/pdps/formularyqafinalmmrevised.pdf (referring to CMS's statutory "responsibility under the Medicare Modernization Act (MMA) to make sure beneficiaries receive clinically appropriate medications so that formularies are not discriminatory").

[7] 80 Fed. Reg. 54,172, 54,172 (Sep. 8, 2015). Consistent with OCR's enforcement of other civil rights authorities, this nondiscrimination proposed rule states that the definition of "Federal financial assistance" does not include Medicare Part B payments made to physicians. *Id.* at 54,195. Notwithstanding that limitation on *physicians'* potential liability

In light of the clear statutory protections against discrimination in healthcare, as well as HHS's responsibility for enforcing those protections, it is wildly inappropriate for CMS, as an agency under HHS, to engage in discrimination or to implement a model that results in discriminatory effects. We are gravely concerned and deeply disappointed that CMS has proposed a model that would have such an overwhelming discriminatory impact on some of our nation's most vulnerable individuals.

b. *Patient Access and Unintended Consequences*

We fear, as well, that the reductions in reimbursements for many drugs under Phase I of the proposed model will result in very serious unintended consequences. The desired result of the model, as expressed by CMS, is that costs will be reduced through the reduced use of "high cost" drugs. CMS admits that the goal of the model is to "test whether the proposed alternative approach for the ASP add-on payment . . . will remove any excess financial incentive to prescribe high cost drugs over lower cost ones when comparable low cost drugs are available."[8] This statement suggests that, under the model's proposed payment cuts, a lower-cost drug would be substituted for a higher-cost drug only if the lower-cost drug were "comparable" for purposes of the beneficiary's condition. This is naïve and unrealistic; by cutting reimbursements so significantly, CMS would discourage the use of higher-cost drugs in ***all*** cases, regardless of whether a "comparable" or appropriate alternative may be available. And, as noted, for many patients with autoimmune disorders and other serious conditions, the unfortunate reality is that a "comparable" alternative will *not* be available. For these patients, for whom access to a full range of treatment options is critical, policies that impose blanket disincentives designed to discourage any "high cost drug" from being prescribed create very real threats to appropriate access. What remains, then, is only a perverse incentive for providers to stop prescribing or providing certain therapies, which, in turn, will work only to deny many patients' access to the drugs upon which they rely to function. This will result in disruptions to care and deteriorating conditions that neither improve quality nor reduce costs.

Significantly, Phase I of the proposed model would severely cut physicians' reimbursement for most Part B drugs from 106% of ASP to 102.5% plus a flat fee. Although CMS states that this phase would be budget neutral, the Proposed Rule fails to account for the rising cost of many drugs. In particular, because the proposed budget neutrality calculation is based on 2014 claims, it effectively freezes the budget at 2014 levels and, as such, will not be budget neutral when implemented.[9] We are concerned that, by ignoring 2015 and 2016 claims, CMS fails to account for the continued rising costs of drugs driven, in part, by new, innovative, high-cost therapies. Although these innovative therapies may have higher costs as compared to other drug therapies, they are often cost-effective over the patient's full pathway of care because, for many patients, these therapies improve their ability to manage their conditions over sustained periods of time, thereby increasing productivity, improving quality of life, and reducing the risk of relapses, deteriorating conditions, disease progression, and disability.

In addition, we understand that the proposed reimbursement rate of 102.5% of ASP would be reduced even further—down to just a fraction of one percent of ASP—through sequestration. With such meager reimbursements, providers will inevitably be left underwater if they prescribe certain therapies. And, due to the nature of ASP-based reimbursement and the "two-quarter lag" before a drug's reported ASP is used for payment purposes, providers will be put even further underwater any time a manufacturer takes even a minor price increase. As we have seen time and again—and as CMS essentially admits is its intended goal for the proposed model—providers do not prescribe drugs for which they are not adequately reimbursed.

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under the nondiscrimination proposed rule, the Medicare program itself is a healthcare "program[] . . . administered by an Executive Agency" and, as such, is well within the letter and spirit of the ACA's nondiscrimination protections.

[8] 81 Fed. Reg. at 13,232.

[9] 81 Fed. Reg. at 13,233.

Phase II of the proposed model also raises serious risks of inadequate reimbursement for many drugs that are medically necessary for our members and other vulnerable Medicare beneficiaries. For example, under Phase II, CMS proposes that it may decide to price an entire class of products at a lower "reference" price, which would effectively negate the prescribing of any drug in the class with a cost that exceeds the Agency's chosen "reference price." This would clearly result in providers avoiding the use of the higher-cost drugs, creating disruptions in care and forcing the use of either no therapy at all or, alternatively, the need to change providers or sites of care, or to use a drug that may cost less but which is less effective for the patient. We are concerned that a number of innovative medicines that treat autoimmune disorders would experience a significant, disproportionate impact under such a policy.

Accordingly, these proposals, if finalized, will have a dramatic effect on patient access and will result in serious care disruptions, disproportionately affecting Medicare's most vulnerable patients. For patients living with serious, complex, and chronic conditions, disruptions in services and lack of access to needed medications can be devastating. Individuals with autoimmune diseases, for example, 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—they result from an aberrant immune response—yet this group of more than 100 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.[10] Indeed, data show that patient responses to immunosuppressants and other immune-modulating therapies vary greatly; as a result, these drugs often are not interchangeable for particular patients and their specific experiences with autoimmunity and other co-occurring conditions.[11] Further, for patients with autoimmunity, treatment options frequently are extremely limited. Given the complex, chronic, and often incurable nature of autoimmune disorders, as well as how they interact with other conditions that a patient might have, access to the full range of available treatments is essential because there is no one drug that is the "highest value," and meaningful access to the full range of possible options is essential.[12]

The clinical (and practical) value of ensuring access to the range of treatment options for conditions where the available therapies are not interchangeable is further underscored by the impact of

[10] *See, e.g.*, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), "Handout on Health: Systemic Lupus Erythematosus," *at* http://www.niams.nih.gov/HEALTH_INFO/LUPUS/DEFAULT.ASP#Lupus_6 (May 2013) (noting that "lupus is different in different people and is characterized by autoimmunity in various systems of the body," and that "[m]any symptoms can come and go overtime," such that a treatment plan must be based on the patient's particular characteristics, such as age, sex, and specific symptoms, and "tailored to the individual's needs"); NIAMS, "Handout on Health: Rheumatoid Arthritis," *available at* http://www.niams.nih.gov/health_info/Rheumatic_Disease/default.asp#ra_10 (April 2013) (describing treatments for rheumatoid arthritis and how they may vary from person to person, and the importance of using "drug combinations instead of one medication alone"); Am. College of Rheumatology, "Sjögren's Syndrome," http://www.rheumatology.org/Practice/Clinical/Patients/Diseases_And_Conditions/Sj%C3%B6gren_s_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).

[11] *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).

[12] *See, e.g.*, FDA, News Release, FDA approves new multiple sclerosis treatment: Tecfidera (Mar. 27, 2013), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm345528.htm ("[N]o drug provides a cure for multiple sclerosis so it is important to have a variety of treatment options available for patients." (quoting the director of FDA's Center for Drug Evaluation and Research Division of Neurology Products)).

co-morbidities in this patient population.[13] Many patients with autoimmune diseases (and other chronic conditions) have multiple conditions and symptoms that require treatment with numerous medicines, often in several classes.[14] The appropriate and effective management of chronic conditions through prescription drugs is best for patients and, in addition, helps to contain healthcare system costs by preventing hospitalizations, reducing the frequency and impact of relapses, and protecting against rapidly deteriorating conditions that can lead to disability. Indeed, the Congressional Budget Office (CBO) recognizes that use of prescription drugs reduces spending for other medical services.[15]

Notably, even the Institute for Clinical and Economic Review (ICER), an organization that CMS cites in the Proposed Rule, does not seem to strongly support a number of the value-based purchasing tools that CMS has proposed to use in Phase II, including "indications-based" pricing. In a white paper released on March 15, 2016, ICER states that, while it recognizes the "intrinsic appeal" of indication-specific models, many "challenges darken the prospects for [indication-specific pricing] in the US."[16] Elaborating on these challenges, ICER's white paper discusses issues such as complex drug purchasing and delivery systems, limitations with drug formulary tiering structures, insufficient data systems, unintended pricing effects based on government price reporting, prohibitions and restrictions concerning off-label indication discussions, and anti-kickback law concerns. Summarizing ICER's own apparent doubts as to the current viability of these proposals, Dr. Pearson, ICER's president, cautioned that "even with the optimism implied by the CMS announcement, there remain significant challenges to designing and implementing these programs in the US. Our white paper emerged after months of investigation of international models and discussion with insurers and manufacturers in the ICER membership program." CMS should not move forward without addressing these very significant challenges as recognized by a multitude of stakeholders and even by ICER.

c. *Rationing*

An additional concern is that the Proposed Rule will result in severe and inappropriate rationing of care. Providers under Part B will be forced to make impossible decisions regarding which patients should receive the most clinically appropriate care at a higher cost (with the provider risking inadequate reimbursement), and which patients will receive less expensive, less appropriate care. While we are well aware that more expensive does not necessarily mean higher quality, the reality is that many new drugs that are more costly (compared to other drugs) significantly improve patients' health and quality of life, thereby delivering tremendous value to beneficiaries and to the Medicare program. In other words, these drugs are more expensive in light of their significant value over course of patients' full pathway of care. Universally restricting access to these therapies under Medicare Part B will not only hinder access and stymie positive outcomes, but also will necessarily result in rationing decisions that aggravate, rather than alleviate, current quality, cost, and disparities issues in our healthcare system. Importantly, too, this consequence of rationing care is tantamount to imposing coverage limitations, which, as discussed in the next section, is beyond the scope of CMMI's authority.

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[13] *See, e.g.*, Alessio Fasano, *Systemic Autoimmune Disorders in Celiac Disease*, Current Opinion in Gastroenterology, 22:674–679 (2006) ("Similar to typical autoimmune disorders, celiac disease has a multifactorial etiology with complex genetics and comorbidity with autoimmune diseases.").

[14] *See, e.g.*, NIH, Progress in Autoimmune Diseases Research 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," *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.").

[15] *See* CBO, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (Nov. 2012).

[16] ICER, *Indication-Specific Pricing of Pharmaceuticals in the United States Health Care System* (Mar. 15, 2016).

III. Legal Concerns

We are greatly concerned that CMS would far exceed its authority in a number of areas if it finalized this model as proposed. First, under Section 1115A of the Social Security Act, CMMI may "test innovative payment and service delivery models." This statutory language—which refers directly and repeatedly to "*payment* and *service delivery* models" (emphasis added)—does not include or permit models that test or impose limitations on *coverage* of drugs and services. As noted above, CMS has stated that a primary goal of the proposed model is to remove financial incentives for physicians to prescribe high cost Part B drugs—which, effectively, means that CMS is trying and intending to discourage physicians from providing these medications to patients. This, in turn, will result in discrimination, access barriers, and rationing of care, all of which are tantamount to the imposition of limits on coverage. But the statute does not allow CMMI to impose coverage limitations. In fact, CMMI is *prohibited* from expanding models that negatively affect coverage. Section 1115A(c)(3) explicitly states that models can be expanded only if, among other conditions, "the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals." It is, therefore, extremely troubling that the Proposed Rule plans to implement—on a nationwide basis—a *two-phase* model that is, under *both* proposed phases, all but certain to deny or limit coverage for many medically necessary drugs. The statute does not permit this.

Second, the implementation of a model that—at the outset—has a "nationwide" scope is clearly inconsistent with CMMI's statutory authority. The statute requires that CMMI models must "address[] a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures"—and that models should be pursued only "where the Secretary determines that there is *evidence* that the model addresses a *defined population*" as described in the statute.[17] Under the Proposed Rule, the model would not be tailored to a defined population as described in the statute and, moreover, would apply nationwide upon initial implementation. This is inconsistent with the statute, which clearly contemplates that "implementation on a nationwide basis" could occur only at the point when a model is *expanded—after* initial implementation and evaluation.[18] And, as noted, the statute specifies particular conditions under which a CMMI model can be expanded.[19] Troublingly, the Proposed Rule ignores these conditions for "expanding" a model and proposes to implement, from the outset, a nationwide test affecting nearly all Medicare Part B beneficiaries and Part B drugs. This is plainly at odds with both the letter and spirit of the CMMI statute.

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[17] SSA § 1115A(b)(2)(A) (emphasis added).

[18] *See* SSA § 1115A(c) (addressing "Expansion of Models" and stating as follows: "Taking into account the evaluation under subsection (b)(4), ***the Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested*** under subsection (b) or a demonstration project under section 1866C, to the extent determined appropriate by the Secretary, if" specified conditions are met).

[19] SSA § 1115A(c). Under this provision, such conditions include all of the following and, further, must take into account the statutorily required "evaluation" of the model consistent with additional statutory criteria for such evaluations (which include specific requirements for analyses of the quality of care provided to beneficiaries under the model and any changes in spending under the applicable title as a result of the model):

> (1) a determination by the Secretary "that such expansion is expected to—(A) reduce spending under [Medicare or Medicaid] without reducing quality of care; or (B) improve the quality of patient care without increasing spending";
>
> (2) a *certification* by the Chief Actuary of CMS "that such expansion would reduce (or would not result in any increase in) *net program spending* under [Medicare or Medicaid]" (emphasis added); and
>
> (3) as noted, a determination by the Secretary that "such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals." In determining which models or demonstration projects to expand under the preceding sentence, the Secretary shall focus on models and demonstration projects that improve the quality of patient care and reduce spending.

It is significant that criterion (2), above, refers to *net program spending*—not just drug costs.

Third, CMS's contemplated timeline for implementing the Proposed Rule, if finalized, is inappropriately compressed and aggressive. We do not see how it is possible for CMS to meaningfully review, evaluate, consider, and respond to the public comments received on the Proposed Rule within a timeframe that would allow Phase I to begin in Fall 2016, as CMS has suggested. This is particularly true given that CMS did not solicit any input from the public or from key stakeholders before issuing the Proposed Rule. The proposed sweeping changes and nationwide scope require further consideration and, pursuant to the Administrative Procedure Act (APA), *meaningful* review of and response to the comments that the Agency has sought and received from stakeholders. Pressing forward under the abbreviated timeline that CMS contemplates under the Proposed Rule would belie any assertion from the Agency that it has thoughtfully considered and responded to stakeholders' input and comments.

IV. Ethical Concerns

Finally, the Proposed Rule raises serious ethical concerns relating to the Agency's ability to conduct experiments involving Medicare beneficiaries. The current structure of the proposed model mandates the participation of all Part B beneficiaries in almost all geographic locations. If finalized, the Proposed Rule would needlessly subject millions of beneficiaries to a nationwide experiment that very likely will have negative consequences, without first obtaining their informed consent. Further, this test carries no apparent benefit to these beneficiaries, other than to gather some data (for Medicare's use, and on Medicare's own terms) and to test a theory regarding the impact of reimbursement cuts.

The Proposed Rule provides no basis for why a nationwide test is necessary, particularly at the outset of the model. The statute clearly contemplates that, initially, models should be implemented as smaller, limited studies, and should later be expanded if, and only if, they are shown *by evidence upon implementation and evaluation* to result in positive effects, or, at the very least, to not cause negative effects, from a cost *and* quality of care perspective.[20] It is deeply troubling that the Proposed Rule seems to bypass all of these procedures and safeguards. While we understand the value of exploring potential ways to improve the delivery of quality care to Medicare patients, the Proposed Rule's heavy handed cuts and broad, untailored application are too drastic to employ simply to test an idea, especially without first demonstrating—on a smaller, more defined scale, and with a far more robust solicitation and consideration of input from key stakeholders, including patients and providers—that the model provides benefits from a quality of care and cost standpoint or, at the very least, does not do harm.

CMS representatives have stated that, although they intend to finalize the proposal, they will continue to evaluate and modify it as needed going forward. This suggests that CMS itself is aware that the proposal will require changes and adjustments as it proceeds. Disappointingly, however, CMS does not provide any guidance or parameters on *how* the model will be evaluated, how its benefits and/or harms will be measured, or how CMS will account for stakeholders' input as that process unfolds.

We also note that, in speaking on a recent panel, Dr. Patrick Conway, who leads the CMMI at CMS, noted that the proposed Part B drug payment model will "need further development and patient input" to help "define what are outcomes that are most meaningful to patients."[21] This statement indicates that the proposed model has not yet been fully developed or vetted, and that its potential effects, including possible unintended consequences, have not been meaningfully assessed, particularly with respect to the impact on vulnerable patients with serious and chronic conditions. While we support

[20] SSA § 1115A(c). Notably, too, the relevant metric with respect to costs is "net program spending" under Medicare—not just drug costs. *See* SSA § 1115A(c)(3) (stating that a CMMI model can be expanded only if, among other criteria, there has been a certification by the Chief Actuary of CMS "that such expansion would reduce (or would not result in any increase in) *net program spending* under [Medicare or Medicaid]" (emphasis added).

[21] Yochelson, M., CMS Will Adjust Part B Drug Model Over Time, Official Says, Bloomberg BNA (April 11, 2016).

CMS' goals of improving quality under the Part B program and seeking to contain healthcare costs, the Proposed Rule's model is premature and lacks sufficient evidence to suggest that the experiment will not negatively impact patients. In essence, CMS is moving forward with a nationwide experiment that does not include adequate protections for informed consent, respect for persons, and an appropriate opportunity for patients and providers to balance the potential risks and benefits to participants.

For these reasons, we respectfully believe that it is not ethical or appropriate to implement a sweeping model that is undeveloped and insufficiently vetted with stakeholders, including the need for "further development and patient input" referenced by Dr. Conway. We strongly urge CMS to take into account our input as well as the comments of additional patient advocate groups, provider organizations, Members of Congress, and other stakeholders, and to withdraw the proposed model. Further consideration must be given to the significant policy, legal, and ethical issues raised by the proposal.

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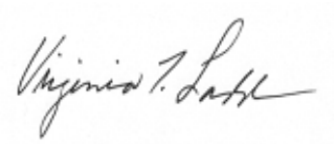
Thank you for your consideration of our comments. We look forward to continuing to work with you on these critically important issues.

Sincerely,



Virginia T. Ladd
President/Executive Director, American Autoimmune Related Diseases Association (AARDA)

On behalf of

American Autoimmune Related Diseases Association

American Behçet's Disease Association

Dysautonomia International

International Foundation for Autoimmune Arthritis

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Sjögren's Syndrome Foundation

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