January 22, 2016

*By Electronic Submission*

The Honorable Ted Nickel

Commissioner, Wisconsin Office of the Commissioner of Insurance

Chair, Regulatory Framework (B) Task Force

125 South Webster Street

Madison, Wisconsin 5370

Ms. Jolie H. Matthews

Senior Health Policy Advisor & Counsel

Regulatory Framework (B) Task Force

National Association of Insurance Commissioners

444 North Capitol St NW #701

Washington, DC 20001

Ms. Jennifer R. Cook

Senior Health Policy Advisor & Legislative Analyst & Counsel

Regulatory Framework (B) Task Force

National Association of Insurance Commissioners

444 North Capitol St NW #701

Washington, DC 20001

**RE: Health Carrier Prescription Drug Benefit Management Model Act, MDL 22**

Dear Commissioner Nickel, Ms. Matthews, and Ms. Cook:

The American Autoimmune Related Diseases Association, Inc. (AARDA) appreciates the opportunity to propose revisions to the National Association of Insurance Commissioners (NAIC) Health Carrier Prescription Drug Benefit Management Model Act (the Model Act).

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 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, 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.

We are pleased that the NAIC has committed to considering revisions to the Model Act, in particular, “to address issues related to: 1) transparency, accuracy and disclosure regarding prescription drug formularies and formulary changes during a policy year; 2) accessibility of prescription drug benefits using a variety of pharmacy options; and 3) tiered prescription drug formularies and discriminatory benefit design.”[[1]](#footnote-1) These are critically important areas, and we applaud the NAIC’s focus on these issues and interest in public comments and consumer input as it considers potential revisions to the Model Act.

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 health care 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 comments and suggested revisions relating to the following key areas of concern:

* Discriminatory Benefit Design and Adverse Tiering;
* Formulary Transparency, Accuracy and Disclosure; and
* Accessibility of Prescription Drugs.

In each of these areas, clear, robust protections and strong oversight and enforcement are necessary, as discussed further below.

1. **Overview: The Need for Updates to the Model Act**

As the NAIC is well aware, dramatic changes to health insurance and prescription drug coverage nationwide have occurred since the Model Act was drafted in 2003, including but not limited to the implementation of Medicare Part D (effective as of January 1, 2006) and significant reforms under the Affordable Care Act (ACA) (enacted in 2010). Both Medicare Part D and the ACA include specific statutory provisions that set standards for prescription drug coverage and prohibit discriminatory practices that would discourage individuals with certain health conditions from enrolling in particular plans. These nondiscrimination requirements are also reflected in relevant regulations and guidance for these programs. For example, under the Medicare prescription drug benefit, Part D plans are required to cover “all or substantially all” drugs in six specified “classes of clinical concern” for which the available therapies are not interchangeable: antineoplastics, immunosuppressants, antidepressants, antipsychotics, antiretrovirals, and anticonvulsants. This formulary protection arose 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.”[[2]](#footnote-2)

As another example, the ACA requires all non-grandfathered plans in the individual and small group markets to provide a package of “essential health benefits” (EHB) that provides specified categories of services, including prescription drugs, and meets additional standards as set forth in the statute and implementing regulations from the Centers for Medicare and Medicaid Services (CMS). The EHB standards include requirements relating to prescription drug benefits[[3]](#footnote-3) and a “[p]rohibition on discrimination” which provides that “[a]n issuer does not provide EHB 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.”[[4]](#footnote-4) We believe that state insurance laws should include similar beneficiary protections, and, accordingly, we have recommended a number of revisions relating to these protections below.

We believe it is particularly important for the NAIC to pursue the revisions we suggest in these comments because gaps remain in the federal regulations and guidance issued by CMS to date, and because we are concerned that there has not been sufficient oversight and enforcement with respect to the ACA’s nondiscrimination protections. Indeed, notwithstanding these protections under the ACA, we have seen plans that limit access to critical medications through narrow formularies that do not follow available treatment guidelines, and that render medications inaccessible through prohibitively high cost-sharing and excessive medication management techniques. We also have seen that a number of plans are placing all or almost all medications to treat a certain condition (particularly high-cost, chronic conditions) on the highest cost-sharing tier—a practice that CMS has also noticed and has identified as being of concern and potentially discriminatory.[[5]](#footnote-5) This practice of “adverse tiering” is particularly harmful to individuals with serious and chronic conditions—including autoimmune patients as well as individuals with mental health disorders, HIV/AIDS, epilepsy, cancer, and others—who rely on prescription medicines to manage their conditions and maintain their ability to function. As discussed below, we urge the NAIC to incorporate additions to the Model Act to address these and other concerns related to prescription drug benefit coverage and transparency.

1. **Discriminatory Benefit Design**

We applaud the NAIC for recognizing that the Model Act should be updated to reflect important protections for consumers against discriminatory benefit designs, and to ensure that the market reforms and consumer protections enacted through the ACA are applied, implemented, and enforced at the state level.[[6]](#footnote-6) Currently, the Model Act does not appear to include any provisions expressly relating to ensuring that plans do not create or implement discriminatory benefit plans or designs. Thus, we believe that NAIC should revise the Model Act to include such provisions.

While our comments focus on the particular importance of nondiscrimination protections for patients with autoimmune disorders and other chronic conditions, we note that these protections are important to all individuals as they help ensure a stable marketplace that does not shift high-cost patients into a few plans, which inevitably fail. The ACA’s protections against discriminatory benefit designs were included not only to promote appropriate access for all consumers, but also to ensure the success and sustainability of the market overall. It is essential that state laws reflect these critical protections that will result in better protections for all consumers and a more stable market for all stakeholders.

Consistent with the ACA, plan benefit designs—including formulary structures, cost-sharing requirements, and medical management techniques—must not be structured or implemented in a manner that discriminates based on an enrollee’s health condition or health needs, nor should benefit designs be structured or implemented in a way that substantially discourages enrollment by patients with particular health conditions or other protected characteristics. Therefore, we believe NAIC should establish minimum, uniform standards for formulary design, enrollee cost-sharing obligations, and reasonable utilization management techniques in order to prevent discriminatory benefit designs or implementation. We offer some suggestions for such standards below.

Definitions and Examples of Discriminatory Benefit Design or Implementation. In revising the Model Act, the NAIC should consider adding definitions to Section 3 for terms such as “discriminatory benefit design,” “discriminatory benefit implementation,” and “adverse tiering.” “Discriminatory benefit design” with respect to prescription drug coverage could be defined, for example, as a benefit design that has the effect, whether intended or not, of discouraging consumers with certain health conditions from enrolling in the plan, or that creates unreasonable barriers to affordable prescription drug access for consumers with specific health conditions. Examples of “discriminatory benefit design” could include, for example, the following:

* Engaging in “adverse tiering,” which could be defined as a placing all or most drugs in the same therapeutic class used to treat a specific medical condition on a high cost-sharing tier.
* Failing to cover all medications recommended by current, available clinical guidelines for a given medical condition.
* Failing to cover the range of medications in classes where the available therapies are not interchangeable.
* Requiring prior authorization for all or most drugs in a class or all drugs that treat a certain condition.
* Employing step therapy or fail first policies that are not supported by available clinical guidelines.

For individuals living with serious, complex, and chronic conditions, including (but not limited to) autoimmune disorders, protections against the practices listed above are necessary to ensure that consumers can receive appropriate access to prescribed therapies, and to protect against formulary restrictions that otherwise would substantially discourage them from enrolling in plans or that would force them to enroll in plans that cannot meet their medical needs.

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 chronic diseases spans a multitude of diverse conditions, from type-1 diabetes to multiple sclerosis. 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.[[7]](#footnote-7) For patients with autoimmunity, immunosuppressants—one of the six “classes of clinical concern” recognized under Medicare Part D—are an important treatment option (and treatment options for autoimmune diseases frequently are extremely limited). Access to the full range of these medicines is necessary in light of patients’ individualized manifestations of autoimmunity and varied reactions to different treatment options. Indeed, data show that patient responses to immunosuppressants vary greatly, and, as a result, these medicines often are not interchangeable for particular patients and their specific experiences with autoimmunity.[[8]](#footnote-8) 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.[[9]](#footnote-9)

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 co-morbidities in this patient population.[[10]](#footnote-10) Many patients with autoimmune diseases (and other chronic conditions) have multiple conditions and symptoms that require treatment with numerous medicines, often in several classes.[[11]](#footnote-11) The appropriate and effective management of chronic conditions through prescription drugs is best for patients and, in addition, helps to contain health care 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.[[12]](#footnote-12)

For these reasons, and to protect appropriate access to therapies for consumers and the overall stability for the market, we encourage the NAIC to add to the Model Act definitions and examples of discriminatory benefit designs and implementation, such as those we have suggested here. We believe these additions are necessary to ensure that restrictive prescription drug coverage does not discourage enrollment in plans by patients with certain conditions who rely on therapies in particular therapeutic classes. Such discouragement is discriminatory and results in access barriers that harm consumers and adverse selection that harms the market as a whole.

Tiering and Coinsurance. Building on the suggested definitions and examples of discriminatory benefit designs and implementation suggested above, we believe the Model Act should directly address health plan formulary tiering and cost-sharing practices, including coinsurance policies, which must not be permitted to impose prohibitive cost-sharing obligations that would have the effect of discouraging enrollment of and/or limiting access for many plan beneficiaries, particularly those with serious and chronic conditions such as autoimmune disorders. We are concerned that many plans are structuring formulary tiers and cost-sharing obligations such that needed medications are financially out of reach. For example, in June 2014, Avalere released *An Analysis of Exchange Plan Benefits for Certain Medicines*, which reported that 86% of Silver plans (in a review of 123 formularies) place all covered drugs, including generics, in at least one therapeutic class on the highest formulary tier. Further, more than 60% of Silver plans reviewed were found to place all covered medications for certain chronic illnesses on the highest formulary tier.

The same study found that, in seven sample classes (which in large part align with the Part D classes of clinical concern), *more than one-third* (39%) of Silver plans reviewed required coinsurance of 40% or more for *all drugs* in at least one class. The classes included in that sample review were rheumatoid arthritis, multiple sclerosis, diabetes, HIV/AIDS, mental health, oncology, and asthma. Of note, rheumatoid arthritis, multiple sclerosis, and type-1 diabetes are all autoimmune disorders. We are deeply concerned about the impact on patients of these tiering and cost-sharing policies. We urge the NAIC to include in its Model Act meaningful limits on plans’ use of coinsurance, and to require that, in any instance where coinsurance is used, the plan must disclose that fact to consumers in advance of enrollment and must include sufficient information for enrollees to determine the relevant cost-sharing amount associated with the specified level of coinsurance. At a minimum, consumers must be provided, in advance of enrollment, with the information needed to discern the amount of cost-sharing associated with specific medications under a particular plan.

We also encourage the NAIC to specify in the Model Act a maximum level of patient cost-sharing per prescription (or per month), in order to prevent situations where patients owe multiple hundreds or thousands of dollars in cost-sharing for a prescribed medicine. This is especially important because a number of plans appear to be using high coinsurance requirements for only certain categories of drugs that treat serious and chronic conditions. We are concerned that cost-sharing structures of this kind are discriminatory as they create access barriers based on an individual’s health condition/needs.

Oversight; Exceptions Process; Transition Fills. The Model Act also should include clear language requiring states to develop and implement an oversight mechanism to ensure that plans do not have a discriminatory benefit design or implementation. Appropriate oversight must include robust and appropriate processes and procedures for complaints, exceptions, and appeals.

We appreciate the current Section 7 of the Model Act, regarding medical exceptions approval process requirements and procedures. Section 7 permits enrollees to request approval for coverage of a drug that was previously denied. In addition to these existing provisions relating to the exceptions process, we believe the Model Act should affirmatively require the State Insurance Commissioner’s Office (or designated personnel) to conduct formulary reviews to ensure that plan benefit designs are not discriminatory. We also believe that an “expedited” exceptions process should be added, which would require plans to make a determination on an exception request within 24 hours in cases of exigent circumstances. This is an important addition because, while we appreciate the Model Act’s current emphasis on timeliness, we are concerned that a time period of 72 hours after the request has been made may be too long for some patients with serious and urgent needs.

We also urge the NAIC to include in the Model Act a provision requiring transition fills, where necessary, when an individual changes plans. This provision should require plans to offer 90 days of coverage for new enrollees for existing medications, without utilization management. For patients with complex chronic conditions, including autoimmune disorders, any gap in treatment can risk harmful and costly consequences for those who are stabilized on particular medications. Because these complex conditions often require a carefully tailored set of multiple drugs, failure to receive one drug in a timely manner can derail a patient’s entire therapy regimen. Therefore, when a newly enrolled patient is stabilized on a particular medication or combination of medications, it is critically important that the plan provide a meaningful transition period that allows sufficient time to assess the available options and to seek a formulary exception or transition to a new medication, where necessary. These processes can be difficult and complicated, and often take time; thus, the 90-day time frame is needed to provide patients with sufficient time to work with their health care providers to pursue appropriate options.

1. **Formulary Transparency, Accuracy and Disclosure**

We applaud the NAIC’s interest in addressing transparency, accuracy and disclosure requirements regarding prescription drug formularies and formulary changes during a policy year. The current Section 6 of the Model Act governs the information provided to prescribers, pharmacies, covered persons and prospective covered persons. While we support Section 6.B regarding information to covered persons and prospective covered persons, we believe additional requirements are needed to ensure timely and detailed information about the drug formulary tiers and costs. For example, currently, cost information, among other critical information, is only required “upon request.”

AARDA strongly supports requiring plans to publish up-to-date, readily accessible and understandable formulary information that not only includes the listing of drugs on each plan formulary and the applicable tier structure, but also clearly specifies any utilization management restrictions that may apply to each drug and the specific cost-sharing obligations—including sufficient information to determine the *amount* of cost-sharing in cases where a coinsurance amount applies (as discussed above). Without knowing the cost of the drug or the dollar amount associated with the coinsurance percentage, consumers have no way to know, or even to estimate, the cost-sharing amounts they will owe for a prescription that is subject to coinsurance. For patients with serious and chronic conditions, access to this cost-sharing information is fundamental to their decision-making process when choosing the coverage option that works best for their health needs. Therefore, we strongly support a requirement for plans to specify all applicable cost-sharing information as part of a formulary transparency requirement. This information must be publicly available and readily accessible prior to enrollment, and must remain up-to-date, publicly available and readily accessible throughout the plan year.

The Model Act also should prohibit plans from removing drugs from their formulary in the middle of a benefit year, absent special circumstances, such as a drug’s discontinuation or withdrawal from the market due to safety reasons. Similarly, the Model Act should clarify that plans may not change a drug’s tier status mid-way through the plan year in a manner that would increase enrollees’ cost-sharing obligations. Currently, Section 6.C appears to permit such changes if notice is provided to enrollees. Importantly, patients make enrollment decisions based on the coverage options as specified *at the time of enrollment*. Plans should not be permitted to change the tiering or cost-sharing status of a drug subsequent to the enrollment period without a safety justification for doing so; to do so would be to change the benefit and cost-sharing requirements mid-year, which issuers should not be allowed to do.

1. **Accessibility of Prescription Drugs**

We support the NAIC’s interest in ensuring that prescription drugs are accessible through a variety of pharmacy options.Our patients often struggle with consistently accessing needed medications at a pharmacy that may be far away. Ensuring patients can receive appropriate, safe medications through mail-order pharmacies, compounding pharmacies, and specialty pharmacies is critical. Since the Model Act was drafted, mail-order, compounding, and specialty pharmacy use has grown significantly and it is important that the NAIC’s revisions reflect those changes to ensure and encourage, as appropriate, the use of such pharmacies for purposes of prescription drug accessibility.

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We appreciate your consideration of our comments, and we look forward to continuing to work with you on these very important issues. We urge swift adoption of revisions, with appropriate notice and comment, to ensure states can begin to consider the revisions as they update their state laws.

Sincerely,



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

1. NAIC, Regulatory Framework (B) Task Force, Summary Report from 2015 Fall National Meeting (Nov. 19, 2015). [↑](#footnote-ref-1)
2. Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5. [↑](#footnote-ref-2)
3. 45 C.F.R. § 156.122. [↑](#footnote-ref-3)
4. 45 C.F.R. § 156.125(a). [↑](#footnote-ref-4)
5. *See, e.g.*, CMS, Draft 2017 Letter to Issuers in the Federally-facilitated Marketplaces, at 49 (stating that “CMS is also concerned about adverse tiering, which occurs when a formulary benefit design assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high cost medical condition to a high cost-sharing tier,” and noting that “adverse tiering is potentially discriminatory”); *see also* CMS, Notice of Benefit and Payment Parameters for 2016 Proposed Rule, 79 Fed. Reg. 70,674, 70,723 (Nov. 26, 2014) (providing examples of potentially discriminatory formulary designs, such as placing most or all drugs for a condition on the highest cost tier). [↑](#footnote-ref-5)
6. This is particularly important given the federal government’s approach to place primary authority for enforcement of these protections with the states, unless or until the state does not adequately enforce. *See e.g.,* CMS, Draft 2017 Letter to Issuers in the Federally-facilitated Marketplaces, at 6 n.6 (“States are the primary regulators of health insurers and are responsible for enforcing the market reform provisions in title XXVII of the Public Health Service (PHS) Act both inside and outside the Marketplaces. Under sections 2723 and 2761 of the PHS Act and existing regulations, codified at 45 CFR Part 150, CMS is responsible for enforcing the provisions of Parts A and B of title XXVII of the PHS Act in a State if the State notifies CMS that it has ‘not enacted legislation to enforce or that it is not otherwise enforcing’ one or more of the provisions, or if CMS determines that the State is not substantially enforcing the requirements.”). [↑](#footnote-ref-6)
7. *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). [↑](#footnote-ref-7)
8. *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). [↑](#footnote-ref-8)
9. *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)). [↑](#footnote-ref-9)
10. *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.”). [↑](#footnote-ref-10)
11. *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.”). [↑](#footnote-ref-11)
12. *See* CBO, “Offsetting Effects of Prescription Drug Use on Medicare’s Spending for Medical Services” (Nov. 2012). [↑](#footnote-ref-12)