



American Autoimmune

Related Diseases Association, Inc.

www.aarda.org

A nonprofit association bringing a national focus to autoimmunity, the major cause of chronic disease

November 19,, 2012

Mr. Boris Bershteyn
Acting Administrator
Office of Information and Regulatory Affairs
725 17th Street, NW
Washington, DC 20503

Dear Mr. Bershteyn:

Almost 50 million Americans suffer from autoimmune diseases; many of them face multiple challenges in obtaining diagnoses and treatment. For these patients, there are two essential elements that must be available: access to specialists and need to access to more than one drug per class.

The vast majority of autoimmune patients have stories that detail visit upon visit to doctors searching for a diagnosis that explains the perplexing and often life-threatening symptoms that afflict them. Their best, in fact, their only hope is access to specialized care and, usually, multiple choices of medication as each case is unique.

The American Autoimmune Related Diseases Association, (AARDA) is the only national nonprofit health agency dedicated to bringing a national focus to autoimmune diseases that include such life-threatening conditions as lupus, multiple sclerosis, scleroderma and crohn's disease, etc.

We understand that the Department of Health and Human Services has requested OMB review a proposed Notice of Proposed Rulemaking regarding the implementation of the Essential Health Benefits (EHB) regulations under the Affordable Care Act. We are writing out of deep concern that these rules may undermine the expressed purpose of the health reform law and, in so doing, cause severe harm to millions of Americans including those suffering from autoimmune disorders.

We are alarmed that the December 2011 bulletin issued by HHS that indicated the EHB rules may allow health insurance companies to provide coverage for only one prescription drug in the various therapeutic classes affecting patients with serious illnesses. Understandably, the intent of this approach would be to contain costs. The end result, though, would be devastating. A rule allowing coverage for just a single prescription drug in critical therapeutic categories does not constitute accessible healthcare.

Patients with autoimmune disorders need access to a range of medication therapies is vital. For individuals with this disease, it is necessary for physicians to construct a medication regimen that both attacks illnesses while also controlling the immune system's ability to attack the body's own tissues. Sometimes this requires a particular approach depending on the individual case. These diseases are treated with a host of immunosuppressant therapies including corticosteroid, anti-inflammatory medications, IVIG and biologics. The point is that the physician and patient must have the latitude to attempt different drug combinations in order to preserve the individual's health, and even their life.

This would be impossible if HHS allows insurers to cover just one prescription drug. In terms of your office's responsibility, you must determine whether these rules are consistent with existing law and with the President's expressed intent. Clearly, such a restrictive rule would fail to clear these bars.

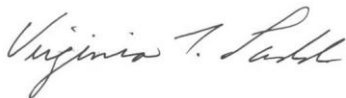
Congress clearly intended that the Essential Health Benefits package in the Affordable Care Act be comparable to a typical employer-provided health plan. It would be hard to find an employer health plan, or even the coverage offered to federal workers under the Federal Employees Health Benefit Program, that has such drastic restrictions on prescription drug coverage or such poorly defined access to a specialist language.

In fact, The Medicare Part D prescription drug program serves as the federal precedent in this regard, ensuring that there is coverage for virtually all drugs in critical therapeutic categories. So, a one-drug approach for the Essential Health Benefit package would mean, without question, that consumers in the ACA health insurance exchanges would receive a substandard level of health coverage. That is unequivocally not the President's intent, nor is it consistent with existing law.

If the EHB rules contain these types of restrictions, we strongly urge you to send them back to HHS on the grounds that they don't meet the minimum legal standards for rulemaking to implement the Affordable Care Act. Allowing such restrictive regulations to take effect would do incalculable harm to the millions of Americans with autoimmune disorders and to the healthcare system, which would see escalating costs as a result of advanced illnesses stemming from poor access to prescription medication which in the case of several autoimmune diseases prevent further damage to joints and organs.

Thank you for your consideration.

Virginia T. Ladd

A handwritten signature in cursive script that reads "Virginia T. Ladd".

President