



July 12, 2017

The Honorable Seema Verma
Administrator, the Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices to Empower Patients (CMS-9928-NC) (RIN 0938-ZB39)

Dear Administrator Verma:

I Am Essential is a broad coalition of patient and community organizations representing millions of patients and their families dedicated to the protection of quality, comprehensive, and affordable health care. We look forward to working with you and the Centers for Medicare and Medicaid Services to ensure that *all* patients have affordable coverage and access to quality care and treatment. As representatives of patients, we, the undersigned 133 organizations offer the following comments in response to your *Request for Information (RFI)* on ways to reduce regulatory burdens and improve healthcare choices to empower patients.

Before responding to the specific questions posed in the RFI, we want to reiterate the importance of health coverage, health benefits and patient protections. While not perfect, the Affordable Care Act (ACA) has provided health coverage and improved access to care for tens of millions of Americans living with chronic and serious health conditions, many of whom were previously uninsured or underinsured. If they lose access and coverage for even one day, their health and well-being can be immediately jeopardized. Therefore, providing them with continuous coverage and consistent care and treatment is paramount. Furthermore,

beneficiaries cannot lose the numerous patient protections contained in the ACA, which have improved access to quality health care.

These patient protections were highlighted in our [letter](#) to Secretary Price dated February 10, 2017 which was signed by 200 patient organizations. These fundamental protections include: the establishment of essential health benefits (EHBs), including prescription drugs and mental health services; the prohibition on coverage exclusions for pre-existing conditions; the requirement that plans cannot use health status as a rating factor; the elimination of annual limits and lifetime limits on coverage for essential health benefits; and the imposition of a maximum annual out-of-pocket cost on EHBs. These protections in the law have proven critical to the health and well-being of patients represented by the organizations in our coalitions. In particular, access to medications is of vital concern to our constituencies, and we strongly urge you to maintain the current essential health benefit regulations that ensure the availability of drugs at a price beneficiaries can afford.

Additionally, the protection afforded people under section 1557 of the ACA, which prohibits discrimination on the basis of race, color, national origin, sex, disability, and age by programs and activities operated or funded by the U.S. Department of Health and Human Services, including Qualified Health Plans, is critical to ensuring access to health care for all Americans. We have particularly focused on potential discrimination in prescription drug formulary design, including inadequate drug coverage, excessive patient cost-sharing and utilization management techniques. We urge you to continue to ensure plans are reviewed and necessary enforcement measures are taken to protect patients from discrimination that results from plan design.

As you make any regulatory changes, we urge you to keep in mind the importance of these critical patient protections. Below are our responses to the specific questions posed in the RFI:

1. Empowering patients and promoting consumer choice. What activities would best inform consumers and help them choose a plan that best meets their needs? Which regulations currently reduce consumer choices of how to finance their health care and health insurance needs? Choice includes the freedom to choose how to finance one's healthcare, which insurer to use, and which provider to use.

- Plans must cover a wide array of prescription drugs that conform to current CCIIO regulations including formularies that follow treatment guidelines and are reviewed by a Pharmacy & Therapeutics (P&T) committee. Plan formularies must be transparent in listing covered drugs and indicating any restrictions or limitations that apply. Formularies cannot be allowed to discourage enrollment by beneficiaries with chronic and serious health conditions, whether by limiting the choice of medications, tiering critical drugs at unaffordable levels, or engaging pharmacy benefit utilization management tools that are unduly onerous.

- Plan formulary tools must enable beneficiaries, while shopping, to look up their prescriptions and learn what plans cover them and at what cost.
- Plans must not impose excessive utilization management techniques that have the effect of discouraging enrollment by people with chronic and serious health conditions.
- Plans should be encouraged and rewarded for using co-payments rather than coinsurance. Patients are confused by the concept of co-insurance. Even for sophisticated consumers, a transparent co-insurance percentage is meaningless if the cost of the drug (the denominator) is not revealed. If a plan uses co-insurance, the patient should be informed of his actual cost in dollars, and the patient's cost should be based on the price actually paid by the plan, not the drug's list price.
- Plans should have no or a low separate deductible for prescription drugs. More plans are imposing extremely high deductibles that make it impossible for beneficiaries to access their medications. Having no or a separate low deductible for prescription drugs will allow patients to access their prescription drugs, which for many with chronic conditions are a daily necessity and can help limit other medical costs.
- Currently, high deductibles or co-insurance must be paid at the beginning of the year, creating a hardship for beneficiaries. It would be beneficial to spread those costs out over 12 months.

2. Stabilizing the individual, small group, and non-traditional health insurance markets.

What changes would bring stability to the risk pool, promote continuous coverage, and increase the number of younger and healthier consumers purchasing plans, reduce uncertainty and volatility, and encourage uninsured individuals to buy coverage?

- It is imperative that the federal government continue to pay for cost-sharing reductions and signal unambiguously that these will remain available. This is the single most important step the federal government could take to stabilize the individual market at this time.
- The premium tax credits must be tied to the beneficiary's income and the cost of care in the beneficiary's geographical region, as well as age. Otherwise, health insurance will be unaffordable for many more people than is currently the case.
- The federal government should enforce the Minimum Essential Coverage requirement that all individuals must have insurance to stabilize the risk pool, and work with stakeholders to ensure everyone can afford a qualifying plan.
- When calculating risk adjustment, CMS should include prescription drug costs, as has been proposed for the calculation of risk adjustment beginning in 2018.

3. Enhancing affordability. What steps can HHS take to enhance the affordability of coverage for individual consumers and small businesses?

- Require plans to use reasonable co-payments instead of co-insurance.

- If a plan uses co-insurance, the patient should be informed of their actual co-insurance amount in dollars, and the patient's co-insurance amount should be based on the price actually paid by the plan, not the drug's list price.
- Encourage or reward plans to exempt prescription drugs from deductibles.
- Require insurers to offer at least one standardized plan that has limited co-payments and that either exempts prescription drugs from the deductible or limits the permissible prescription drug deductible.

4. Affirming the traditional regulatory authority of the States in regulating the business of health insurance. Which HHS regulations or policies have impeded or unnecessarily interfered with States' primary role in regulating the health insurance markets they know best?

- We do not believe that HHS has impeded or interfered with the role of states in the regulation of health insurance. In fact, it is our view that federal laws, regulations, reviews, and enforcement are necessary to protect beneficiaries. Many states lack the financial resources and/or legal authority to prospectively review plans and formularies to ensure that they are adequate and do not discriminate against beneficiaries. Some states have stated they have no interest in or a limited capacity to implement plan requirements included in the ACA, including the important patient protections.

States often rely on consumer complaints to monitor insurance plans. This is not the way our health insurance system should be working. This lack of oversight places the burden on the consumer and their advocates in every state. This often leaves beneficiaries without the protection they need and adequate relief from certain practices of insurance plans. Beneficiaries need federal protections and enforcement, while the states need the federal assistance.

I Am Essential looks forward to working with you and your team at CMS to review the current law and identify areas for improvement. We must caution, however, that in doing so you do not weaken existing patient protections and return chronically ill patients to the situation that existed prior to implementation of the ACA when they could not obtain or access health insurance or health coverage and faced widespread discrimination. We look forward to assisting you in building on the progress that has been made to ensure affordable and quality health care and treatment for all Americans, especially those living with chronic and serious conditions.

Should you have any questions or wish additional information, please contact: Carl Schmid, Deputy Executive Director, The AIDS Institute, cschmid@theaidsinstitute.org; Beatriz Duque Long, Senior Director, Government Relations, Epilepsy Foundation, bduquelong@efa.org; or Andrew Sperling, Director of Federal Legislative Advocacy, National Alliance on Mental Illness, asperling@nami.org. Thank you.

Sincerely,

ADAP Advocacy Association (aaa+)
Adult Congenital Heart Association
AIDS Action Baltimore
AIDS Alliance for Women, Infants, Children,
Youth & Families
The AIDS Institute
American Association on Health and
Disability
American Autoimmune Related Diseases
Association
American Behcet's Disease Association
(ABDA)
American Lung Association
American Sexual Health Association
American Society for Metabolic and
Bariatric Surgery
Arthritis Foundation
Association of Asian Pacific Community
Health Organizations (AAPCHO)
Bronx Lebanon Hospital Family Medicine
California Hepatitis C Task Force
Cancer Support Community
Caregiver Action Network
Center for Independence of the Disabled
Chronic Disease Coalition
Clinical Social Work Association
Colorado Federation of Families
Community Access National Network
(CANN)
Community Catalyst
Crohn's & Colitis Foundation
Doctors for America
Dysautonomia International
Easter Seals Massachusetts
Epilepsy Foundation Alabama
Epilepsy Foundation Arizona
Epilepsy Foundation California
Epilepsy Foundation Central & South Texas
Epilepsy Foundation Chesapeake Region

Epilepsy Foundation Colorado
Epilepsy Foundation Connecticut
Epilepsy Foundation Delaware
Epilepsy Foundation East Tennessee
Epilepsy Foundation Eastern Pennsylvania
Epilepsy Foundation Florida
Epilepsy Foundation Georgia
Epilepsy Foundation Greater Cincinnati and
Columbus
Epilepsy Foundation Greater Chicago
Epilepsy Foundation Greater Los Angeles
Epilepsy Foundation Greater Southern
Illinois
Epilepsy Foundation Hawaii
Epilepsy Foundation Heart of Wisconsin
Epilepsy Foundation Indiana
Epilepsy Foundation Kentuckiana
Epilepsy Foundation Long Island
Epilepsy Foundation Louisiana
Epilepsy Foundation Metropolitan New York
Epilepsy Foundation Michigan
Epilepsy Foundation Minnesota
Epilepsy Foundation Mississippi
Epilepsy Foundation Missouri and Kansas
Epilepsy Foundation Nevada
Epilepsy Foundation New England, Inc.
Epilepsy Foundation New Jersey
Epilepsy Foundation North Carolina
Epilepsy Foundation North/Central Illinois,
Iowa, Nebraska
Epilepsy Foundation Northeastern New
York
Epilepsy Foundation Northwest
Epilepsy Foundation of Southeast
Tennessee
Epilepsy Foundation Oklahoma
Epilepsy Foundation Texas –
Houston/Dallas-Fort Worth/West Texas
Epilepsy Foundation Utah

Epilepsy Foundation Vermont
Epilepsy Foundation Virginia
Epilepsy Foundation Western Ohio
Epilepsy Foundation Western Wisconsin
Epilepsy Foundation of Western/Central
Pennsylvania
Fabry Support & Information Group
FORCE: Facing Our Risk of Cancer
Empowered
Global Healthy Living Foundation
HCSP/HCV Advocate
Healthy Women
Hemophilia Association of the Capital Area
Hepatitis C Allies of Philadelphia (HepCAP)
Human Rights Campaign
IFAA - International Foundation for
Autoimmune & Autoinflammatory Arthritis
International Pain Foundation
International Pemphigus & Pemphigoid
Foundation
Lakeshore Foundation
Let's Talk About Change
Liver Health Connection
Lupus Alliance of Upstate New York
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Lupus Foundation of Southern California
Lupus LA
MANNA
Men's Health Network
Mental Health Colorado
Miles for Migraine
MLD Foundation
National Alliance on Mental Illness
National Alliance on Mental Illness of
Washington State
National Association of Hepatitis Task
Forces
National Association of Nutrition and Aging
Services Programs (NANASP)

National Association of Social Workers
National Fibromyalgia & Chronic Pain
Association
National Hispanic Medical Association
National LGBTQ Task Force
National Medical Association
National Multiple Sclerosis Society
National Organization for Rare Disorders
(NORD)
National Patient Advocate Foundation
National Physicians Alliance
National Stroke Association
National Viral Hepatitis Roundtable
NBIA Disorders Association
New Jersey Association of Mental Health
and Addiction Agencies, Inc.
New Yorkers for Accessible Health Coverage
Obesity Action Coalition
Obesity Medicine Association
The Obesity Society
Out2Enroll
Peer Coach Academy Colorado
Physicians for Reproductive Health
Positive Women's Network - USA
Prevention Access Campaign
Project Inform
Rush To Live
Society for Public Health Education
South Carolina HIV Task Force
Southern AIDS Coalition
Southern HIV/AIDS Strategy Initiative (SASI)
U.S. Pain Foundation
United Spinal Association
The Veterans Health Council
Vietnam Veterans of America
Virginia Organizing
The Well Project
Wellness and Education Community Action
Health Network