December 15, 2014

The Honorable Fred Upton
Chairman

The Honorable Diana DeGette
Representative

Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Representative DeGette,

Thank you for the opportunity to comment on the Energy and Commerce Committee's *21st Century Cures* initiative. The Medicare Access of Patients Rx (MAPRx) Coalition is the leading beneficiary advocacy coalition for Medicare Part D. Founded in 2005, MAPRx brings together more than fifty-five national patient, beneficiary, caregiver, and health professional organizations devoted to helping people with chronic diseases and disabilities who rely upon prescription medications obtained through Part D.

The Medicare prescription drug benefit is a critical lifeline to millions of Medicare beneficiaries by providing access to prescription drugs. Prescription drugs improve health outcomes and save money, when used as directed. Researchers found that implementation of the Medicare prescription drug program was followed by a decrease of more than $1,200 in nondrug medical spending among those who previously had limited drug coverage. While not perfect, Part D's success and popularity suggests that the program is working well for many Medicare beneficiaries.

The 21st Century Cures initiative presents the perfect opportunity to improve upon a successful program. MAPRx developed a set of guiding principles for prescription drug benefit design that set forward recommendations for improvements to the Part D program. The principles are attached for your review.

Thank you for spearheading this important effort to take steps towards improving the lives of all Americans. If you have any questions or wish to discuss the MAPRx principles in more detail, please contact Bonnie Hogue Duffy, MAPRx Coalition Convener, at bonnie@maprxinfo.org or (202) 429-4017.

Sincerely,

Allergy & Asthma Network

Alpha-1 Foundation

American Association on Health and Disability

American Autoimmune Related Diseases Association

Arthritis Foundation

COPD Foundation

Depression and Bipolar Support Alliance

Epilepsy Foundation

GIST Cancer Awareness Foundation

HealthHIV

Hemophilia Federation of America

International Foundation for Autoimmune Arthritis

Lupus Foundation of America

Men's Health Network

Mental Health America

National Alliance for Caregiving

National Alliance on Mental Illness

National Council for Behavioral Health

National Kidney Foundation

National Organization for Rare Disorders

National Psoriasis Foundation

Parkinson's Action Network

RetireSafe

Society for Women's Health Research

United Spinal Association

ABOUT MAPRX

MAPRx is a coalition of patient, family caregiver and health professional organizations committed to safeguarding the well-being of patients with chronic diseases and disabilities who rely on Medicare Prescription Drug Coverage. MAPRx member organizations advocate on behalf of these beneficiaries and collaborate with national and state policymakers to ensure they have the access to the medication therapies they need and deserve.

The Principles

I. Plans should be required to have a **robust formulary and provide coverage for a variety of medications in each drug class or category**.

II. Coverage should be required for Medicare Part D's six protected classes of drugs and any additional classes where restricted access to those drugs would have significant health consequences.

III. Oversight of a prescription drug benefit should include monitoring of:

- **Plan operations** with an emphasis on key performance measures such as frequency and types of complaints, timeliness and resolution of appeals, completeness of enrollment information accessible to pharmacists, and availability of changes to drug pricing;
- **Formulary design** to determine that appropriate access is afforded to physician prescribed treatments and to ensure that the formulary does not discriminate or discourage enrollment by certain beneficiaries;
- **Plans' use of utilization management tools** such as prior authorization, quantity limits and step therapy (where a lower cost drug is tried first before a higher cost drug may be used), should be required to meet best practice standards and appropriate treatment guidelines;
- **Quality measures** should be meaningful to help beneficiaries make an informed drug plan choice and provide CMS necessary information in its oversight role. Measures should include customer service, access to needed drugs, appeal and denial rates, beneficiary protections and overall satisfaction; and,
- **Pharmacy and therapeutic (P&T) committee membership, including robust consumer representation, as well as process and procedural requirements** should ensure access to medically necessary medications. These requirements should include procedural safeguards and timely review of every newly FDA-approved drug so that beneficiaries do not encounter barriers, such as potentially long and unnecessary delays, that hinder their access to medication therapies.

IV. Plans should be required to provide clarity and transparency on coverage and on consumer's out-of-pocket costs. A mix of co-payments and coinsurance can cause significant confusion especially for individuals on multiple and/or expensive medications trying to navigate the system and compare plans. The ability to understand the benefits provided in a plan, along with coverage levels and out-of-pocket costs is an important factor for consumers when making a determination of which plan best meets their needs.

V. Notice of non-coverage, appeals and exceptions process should be simple and understandable. Enrollees should be given timely notice of the reasons for the denial of drug coverage and their appeal rights, including the right to an expedited review. Regulatory oversight should ensure sufficient consistency in exceptions processes among all plans so that providers can assist beneficiaries in an efficient and effective manner.

VI. Rigorous oversight of medication utilization management tools (such as medication substitution, step therapy or quantity limits) is critical.

- Insurers should not be allowed to override a health care provider's practice of medicine by forcing utilization of certain medications or therapies that may be inappropriate to the care of their patients.
- Plans should provide information and transparency about their utilization management tools, including notice of plan changes and the right to appeal.
- Plans should provide clear, relevant patient information on the use of utilization management tools prior to enrollment.

MAPRx Recommendations for Medicare Part D

MAPRx urges policymakers to learn from the experience with Medicare Part D – build on its successes and improve on its limitations. To that end, we encourage the use of the following principles to guide the design of prescription benefit programs. We also encourage policymakers to improve on the limitations of Part D.

- **Plans should be required to have a robust formulary and provide coverage for a variety of medications in each drug class or category.**
- **Coverage should be required for Medicare Part D's six protected classes of drugs and any additional classes where restricted access to those drugs would have significant health consequences.**
- **Oversight of a prescription drug benefit should include monitoring of: plan operations, formulary design, plans' use of utilization management tools, quality measures, and pharmacy and therapeutic (P&T) committees.**
- **Plans should be required to provide clarity and transparency on coverage and on consumer's out of-pocket costs.**
- **Notice of non-coverage, appeals and exceptions process should be simple and understandable.**
- **Rigorous oversight of medication utilization management tools (such as medication substitution, step therapy or quantity limits) is critical to patients' timely access to prescription drugs.**

Limitations of Medicare Part D

Medicare Part D is by no means perfect – key limitations prevent beneficiaries from taking full advantage of the benefits of prescription drug therapy. Policymakers should understand the limitations of Part D and not replicate them:

I. Prohibit gaps in coverage, as they result in beneficiaries modifying their drug use by stopping or reducing their use of certain medications. From 2006, when the Medicare Part D drug benefit took effect, to 2011, beneficiaries were required to pay 100 percent of their drug costs after their total drug spending exceeded an initial coverage limit until they qualified for catastrophic coverage. Researchers have found some beneficiaries discontinue their drug therapy during the coverage gap. Fortunately, the *Affordable Care Act* closes this coverage gap by 2020.

II. Avoid Onerous Cost-Shifting onto Beneficiaries. Many Medicare prescription drug plans have added to their formulary a "specialty tier" for high-cost medications. Unlike lower cost medications, for which beneficiaries usually pay a set co-pay amount, these medications are subject to significant coinsurance, meaning that beneficiaries must pay a percentage of the medication's cost. For drugs in the specialty tiers, this amount can be anywhere from 25-33%, leaving patients to pay thousands of dollars out-of-pocket for cost prohibitive drugs and biologics used to treat cancer, multiple sclerosis, hemophilia,

lupus, rheumatoid arthritis, and other conditions. For many beneficiaries, the result is that they are denied access to the most appropriate, useful medication due to the fact that it is financially out of reach. For those who can afford the drugs, they pay enormous sums out of pocket to maintain their health.

III. Curb the Use of Restrictive Medication Utilization Management. Many Part D plans now employ medication utilization management tools, such as prior authorization, medication substitution or quantity limits that restrict a beneficiary's access to drugs. For example, a "fail first" policy requires that beneficiaries prescribed an expensive medication must first use a less expensive or plan preferred medication, experience that medication failure first before the plan will pay for the original prescription. These policies place unnecessary barriers to patients' access to the medications recommended by their physicians. For many health conditions, such policies threaten patients' lives, safety and medical stability.

IV. Improve program effectiveness, including access, for beneficiaries eligible for low-income subsidies. Medicare makes additional payments to plan on behalf of beneficiaries entitled to subsidies due to low income and asset levels (often referred to as "LIS beneficiaries.") The asset test is a particular barrier for many low-income beneficiaries who need help paying for coverage. Despite outreach efforts, not all eligible beneficiaries have enrolled. In addition, a large number of beneficiaries are required to change plans each year because the premium for their current plan no longer falls below the low-income subsidy level. Changing plans can cause disruption to continuity of care.

V. Improve beneficiary education, decision-making and assistance for choosing the Part D plan best for them. Beneficiaries need to be well informed and compare options in order to make the market work well. However, a June 2012 report from the National Bureau of Economic Research found that fewer than 10 percent of individuals enrolled in what would be for them the most cost effective Part D plan. More needs to be done to encourage beneficiaries to shop around and to provide beneficiaries with the tools and support needed to make well-informed decisions. In its March 2012 Report, MedPAC states that only about 6 percent of beneficiaries switched plans voluntarily.