



June 23, 2011

The Honorable Max Baucus  
Chairman  
U.S. Senate Finance Committee  
Washington, DC 20510

The Honorable Orrin Hatch  
Ranking Member  
U.S. Senate Finance Committee  
Washington, DC 20510

Dear Senator Baucus and Senator Hatch –

MAPRx is a coalition formed in response to the passage of the Medicare Modernization Act, which created the Medicare Prescription Drug program (Part D). MAPRx brings together beneficiary, family caregiver and health professional organizations committed to improving access to prescription medications and safeguarding the well-being of beneficiaries with chronic diseases and disabilities who are enrolled in Part D.

As the Finance Committee today begins consideration of the long-term future of entitlement programs such as Medicare, MAPRx is writing to urge that you consider the very critical needs of people with chronic conditions who rely on the Part D program for access to life-saving and/or life-changing medications. As a group, we recognize the very real need to address the challenging fiscal situation facing the nation. However, we strongly believe that savings cannot and will not be achieved by significant cuts to Medicare, particularly Part D, that restrict or eliminate access to medications that help beneficiaries better manage chronic conditions and innovative, breakthrough therapies that address complex diseases with few if any treatment options. On the contrary, such draconian measures may have immediate returns but drastic long-term consequences for beneficiaries, the Medicare program and the nation.

As the Committee focuses on the future of Medicare and the need to control costs, MAPRx asks that you recognize the importance of these specific issues:

- Avoid onerous cost-shifting that places financial burdens on beneficiaries;
- Allow Medicare beneficiaries to request tiering exceptions for drugs placed on specialty tiers;
- Limit or eliminate restrictive medication utilization management;
- Retain the six protected classes;
- Eliminate the two-year eligibility wait period; and
- Ensure comparative effectiveness research does not restrict access.

### **Avoid Onerous Cost-Shifting onto Beneficiaries**

Unfortunately, this practice already occurs in the Part D program as more and more 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 co-insurance, meaning that beneficiaries must pay a percentage of the medication’s cost. For drugs on the specialty tier, this amount can be anywhere from 25-33%, leaving patients to pay thousands of dollars out of pocket for the very expensive drugs and biologics used to treat cancer, multiple sclerosis, hemophilia, 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.

MAPRx is extremely concerned about the current levels of cost-shifting occurring in the Part D program. We strongly believe that no one relying on Part D should be denied access to needed medications simply because they cannot afford them. Furthermore, this has negative consequences for the Medicare system as a whole. As people do not get the best, most appropriate medications for their condition(s), their health outcomes will be less than ideal, often resulting in dramatically higher costs in the other parts of Medicare.

MAPRx urges the Committee to resist imposing additional burdensome cost-sharing on Part D beneficiaries as a cost-saving strategy for Medicare.

### **Allow Part D Beneficiaries to Request Exceptions for Specialty Tier Drugs**

The Medicare Modernization Act of 2003 requires that if a Part D plan utilizes a tiered cost-sharing structure to manage its Part D drug benefits, the plan must establish and maintain reasonable and complete exceptions procedures that permit enrollees to obtain a non-preferred drug at the more favorable cost-sharing terms applicable to drugs in the preferred tier (Public Law 108-173-Dec. 8, 2003, 117 STAT.2090)

The Center for Medicare and Medicaid Services (CMS) has allowed drug plans to utilize specialty tiers for drugs with a monthly cost threshold at or above \$600, but the agency promulgated regulations that allow plans not to apply exception procedures for such tiers. MAPRx members believe this is a direct contradiction of Congressional intent when passing the Medicare Modernization Act, and we urge Congress to restate its legislative intent to provide beneficiary protections for qualified prescription drug coverage.

### **Limit or Eliminate Restrictive Medication Utilization Management**

In addition to higher cost-sharing, many Part D plans now employ medication utilization management tools, such as prior authorization, medication substitution or quantity limits, to control costs. One of the most troubling policies is “fail first,” which requires that beneficiaries prescribed an expensive medication first use a less expensive medication and find it does not work before the plan will pay for the original prescription.

These policies are designed to control costs by placing unnecessary barriers to patients accessing the medications specifically recommended by their doctor. Not only are these policies a complete infringement on the doctor-patient relationship, they are extremely shortsighted, undermining the health and well-being of beneficiaries. Requiring patients to potentially see their health deteriorate before they gain access to a doctor-prescribed treatment harms the beneficiary and increases the overall costs to the Medicare program. Neither is worth the short-term cost-saving gain.

These policies should be severely limited in the current Part D structure but must not be expanded as a cost-saving strategy going forward. MAPRx strongly recommends that the Committee avoid such policies as it considers ways to ensure continued solvency for Medicare.

### **Retain the Six Protected Classes**

Guidance from CMS directs Part D plans to cover all or substantially all of the drugs in six protected classes: anti-neoplastics, immune suppressants, anti-retrovirals, anti-convulsants, anti-depressants, and anti-psychotics. This ensures that beneficiaries living with chronic conditions have access to the full range of treatments, thereby guaranteeing that they can get the best therapy as recommended by their physician. CMS has in the past proposed – but did not implement – changes to the regulations that included an exception to the requirement to cover “all” drugs in a class.

MAPRx opposes any weakening of the protected classes, which would only serve to place another barrier between beneficiaries and the medications they need. Placing limits on the covered drugs under the protected classes could potentially be seen as a cost-saving strategy. Like medication utilization management policies, such an approach would be shortsighted and counterproductive. MAPRx asks that the Committee avoid any attempt to place limits on the protected classes as a means of cost reduction.

### **Eliminate the Two-Year Waiting Period for Medicare**

In addition to providing health care coverage for Americans over 65, Medicare covers nearly 7 million people with severe and permanent disabilities who receive Social Security Disability Insurance (SSDI) benefits. However, those receiving such benefits must wait two years from their initial eligibility for SSDI

until they are eligible for Medicare. This two-year waiting period exposes millions of Americans to financial strain as well as pain and suffering. Congress has already acknowledged that the waiting period is catastrophic or even life-threatening for some by eliminating it for people with amyotrophic lateral sclerosis (Lou Gehrig's disease) and end-stage renal disease.

MAPRx believes it is time to spare anyone who qualifies as disabled from such consequences by eliminating the two-year waiting period for all. While this delay may save money initially, it likely increases overall Medicare costs by virtually ensuring that those receiving SSDI are suffering poorer health outcomes when they finally do become eligible for Medicare. MAPRx asks the Committee to consider overturning or at least easing this perverse policy as a means to both improve patient care and place Medicare on stronger financial ground.

### **Ensure Comparative Effectiveness Research Does Not Restrict Access**

Comparative effectiveness research, which seeks to evaluate similar treatments or therapies, must not be allowed to determine coverage or reimbursement of treatment or interfere with a physician's ability to determine the best treatment in consultation with their patient. Although MAPRx supports funding for efficacy studies of various treatment options, we are aware of the limitations of such research, which may not take into account variations among individuals and subpopulations in any patient community. Evaluation of treatments, used to guide the medical community, must occur in real healthcare settings to determine their impact on individuals and various unique subpopulations such as those with chronic illness or disability.

Although widely viewed as a tool to make the health care system more consistent, safe, efficient, and affordable, comparative effectiveness research should never be used to deny coverage for drugs or treatments. MAPRx asks that the Committee reemphasize its commitment to this approach, as stated in the Affordable Care Act language related to this issue. It must remain a top priority that beneficiaries have access to the medications needed to improve or maintain their health, as was the intention of the Part D program.

MAPRx is aware of the very difficult fiscal environment facing the nation and appreciates the challenges the Committee confronts as it attempts to both control costs and ensure the long-term viability of Medicare. However, we must also state our concern regarding potential cuts or policies that may produce savings in the near term only to harm beneficiaries and ultimately drive up costs. It is essential that any steps to address costs in Medicare be thoughtful, well-planned, and, ultimately, constructed with beneficiaries in mind.

MAPRx thanks the Committee for the opportunity to provide these comments and recommendations. Furthermore, MAPRx and its members look forward to continued engagement with the Committee on ways to improve the Part D

program so that it better serves current and future beneficiaries. For questions related to MAPRx or the above comments, please contact Mary Beth Buchholz, Convener, MAPRx Coalition, at (202) 637-9732 ext 229 or [Marybeth@maprxinfo.org](mailto:Marybeth@maprxinfo.org).

Sincerely,

The AIDS Institute

The ALS Association

American Autoimmune Related Diseases Association

American Society of Consultant Pharmacists

Arthritis Foundation

Easter Seals

Epilepsy Foundation

Hemophilia Federation of America

The Lupus Foundation of America

Men's Health Network

Mental Health America

National Alliance on Mental Illness (NAMI)

The National Grange

National Kidney Foundation

National Multiple Sclerosis Society

National Osteoporosis Foundation

National Psoriasis Foundation

Parkinson's Action Network

RetireSafe

United Spinal Association