



March 5, 2010

Ms. Charlene M. Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Ms. Frizzera:

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 under Medicare Prescription Drug Coverage (Part D). On behalf of millions of Medicare beneficiaries with chronic conditions who rely on Part D for essential medications, the MAPRx Coalition appreciates this opportunity to submit comments in response to the 2011 Draft Call Letter.

Specifically, MAPRx would like to address the following issues raised in the Draft Call Letter:

- Reassignment of Low Income Subsidy (LIS) recipients who have previously chosen Part D plans (“choosers”) based on premium liability;
- Curbing waste of unused drugs;
- The established price threshold for prescription medications to be included on the Specialty Tier in Part D plans’ formularies; and
- The calendar outlining deadlines leading up to Coverage Year (CY) 2011.

In addition, MAPRx would like to address two issues vital to the communities we represent that were not specifically raised in the Draft Call Letter. First, we urge CMS to maintain and strengthen the six protected classes of treatments (antineoplastics, immune suppressants, anti-retrovirals, anti-convulsants, antidepressants, and antipsychotics). It is critical that beneficiaries continue to have access to the full range of therapies within these six classes in order to pursue the optimal management of their conditions. Second, MAPRx remains concerned about the issue of increasingly burdensome cost-sharing for beneficiaries. While the issue of cost-sharing for medications on the specialty tiers has received a great deal of attention, this is a problem facing all beneficiaries for treatments on all plan formulary tiers. The increasingly common mix of copayments and coinsurance is particularly noteworthy in this respect as coinsurance generally places

more of the cost on consumers. We urge CMS to conduct vigilant plan oversight on this issue to alleviate the financial burden placed on Part D beneficiaries, many of whom are on limited incomes and can least afford expensive drug treatments.

Reassignment of Low Income Subsidy (LIS) “Choosers” Based on Premium Liability

The CY 2011 Call Letter states that CMS is considering reassigning LIS “choosers” who in 2011 will be in plans with premiums equal to or greater than \$10 per month, noting that such beneficiaries may not be aware that they have lower cost alternatives. Beneficiaries would have to affirmatively notify their current plan in order to remain with it.

MAPRx applauds CMS for its efforts to maximize the value of the Part D benefit for the LIS population and to promote savings for the Medicare program in general. We are supportive of this policy change based on a monthly premium threshold of \$10, provided it is implemented in a manner that provides the most comprehensive benefit to the 700,000 LIS beneficiaries estimated to be impacted and that it is effectively communicated to minimize any disruption or negative consequences for individuals.

The Call Letter states that CMS is “considering” using medication history as part of the criteria for reassignment for the LIS choosers, which we believe to be critical to the success of this proposed policy. The coalition strongly urges CMS to adopt “intelligent” or “responsible” reassignment, which would require looking beyond simply the premium cost to consider other factors that may impact a beneficiary’s choice of plans. MAPRx believes that it is essential that each person’s medication history be incorporated into the reassignment decision to ensure that they are in a plan that is not only less expensive but best meets their treatment needs. If this is not done and the new plan’s formulary does not include a beneficiary’s medications, the person could suffer disrupted care that potentially undermines their health. This could occur due to the need to engage in an appeals process to obtain coverage of drugs or utilization management tools, such as prior authorizations, therapeutic substitution or step therapy, that force them to engage in a trial and error period on other medication.

Furthermore, MAPRx urges CMS to utilize intelligent/responsible reassignment for ALL LIS beneficiaries, not only those designated as “choosers.” Reassignment done in this manner has potential to provide substantial benefits to those subject to it; those benefits should not be limited to a specific group within the larger community of LIS beneficiaries.

Successful implementation of intelligent/responsible reassignment will require clear, effective, timely and repeated communication to beneficiaries about upcoming changes to their existing and proposed alternative plans. It is critical that CMS provide early and perhaps repeated notice about plan reassignment in a manner that engages recipients and makes them aware of how and when they will be affected. Such communications must include not only premium amounts but also information on both plans’ formularies and

medication utilization management requirements. Beneficiaries must be clearly informed of their option to remain with their existing plan and the requirement to act affirmatively to do so. Ideally, beneficiaries should receive notice prior to the initial date permitting sponsors to market Part D plans leading up to open enrollment.

Intelligent/responsible reassignment of LIS beneficiaries, whether “choosers” or not, must be implemented carefully to avoid confusion and disruption to necessary treatment regimens. The initial experience of reassigning dual-eligibles from Medicaid to Part D plans in 2006 and the annual reassignment of LIS beneficiaries provide instructive lessons. Beneficiaries and pharmacists have been confused, leading to problems obtaining medications. We should learn from these experiences to ensure that expansion of reassignment and implementation of additional criteria for the process are effectively communicated and done in a way that appears seamless to beneficiaries.

Curbing Waste of Unused Drugs

In an effort to control costs and reduce waste associated with the Part D benefit, CMS proposes in the CY 2011 Call Letter to request that “Part D sponsors consider allowing beneficiaries in the community setting the option to request a trial supply of no more than 7-14 days of a Part D covered medication when first prescribed.” The Call Letter adds that plans would be expected to prorate cost share amounts for the shorter-term prescription.

MAPRx is generally supportive of this policy change, provided that it remains an option for plan enrollees rather than a plan requirement. CMS has identified several potential benefits to the policy that MAPRx believes will prove valuable to beneficiaries with chronic conditions. These include promoting savings to the beneficiaries, Part D plan sponsors and the Medicare system and preventing beneficiaries from starting medications that may not ultimately be compatible with their Part D plan’s formulary.

As noted previously, MAPRx would like to see this policy change adopted as long as it remains optional. We feel it must not become a medication utilization management tool that is employed for all plans and beneficiaries. Should that happen, there would be the potential for unintended negative consequences for Part D beneficiaries. For example, it would place an additional burden on beneficiaries who are homebound or live in rural areas that lack a nearby pharmacy by requiring multiple visits to the pharmacy to obtain needed medication. It could also serve to inadvertently disrupt or undermine the treatment and management of beneficiaries’ chronic conditions. In some cases, a short-term prescription may not be sufficient to determine therapeutic benefit or identify negative side effects or drug interactions.

The Call Letter refers to CMS data showing that up to 30% of first prescriptions for chronic medications are not refilled as a reason for this policy change. MAPRx believes that there needs to be further exploration and understanding of the reasons beneficiaries are not seeking refills. It is important to understand if this is occurring because of side effects, drug interactions or other negative consequences or if financial considerations are

paramount. If beneficiaries are not refilling prescriptions due to the cost-sharing burden, short-term trial periods for new prescriptions will not address this problem.

Price Threshold for Specialty Tier Medications

For CY 2011, CMS will maintain the \$600 threshold for drugs placed on the specialty tier in Part D plans. This will be the fourth year that the amount remains at \$600. Because of plan provisions unique to the specialty tier, the threshold for drug inclusion is of vital concern to MAPRx and the communities it represents. Beneficiaries have no medication alternatives for therapies included on the specialty tier and there is no appeals process by which beneficiaries can request that a specialty tier drug be placed on a lower cost-sharing tier. For these reasons, MAPRx asks that CMS raise the cost threshold for inclusion on the specialty tier for CY 2011. The recent Government Accountability Office report *Medicare Part D: Spending, Beneficiary Cost Sharing and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier* found that in 2007, \$1100 per month was the utilization-weighted average of the median negotiated price of all specialty tier drugs. MAPRx requests that CMS raise the threshold to an amount more in line with this figure.

MAPRx has strong concerns about the continuation of this threshold. We seek greater clarity from CMS on the rationale for utilizing \$600 as the baseline figure for inclusion on specialty tiers. Furthermore, MAPRx questions why the threshold has not increased over the past three years. Many innovative therapies for the hardest to treat conditions are currently in development and likely to end up on the specialty tier if the threshold remains unchanged. Retaining the \$600 threshold fails to recognize this fact and has the effect of increasing the number of medications eligible for inclusion on specialty tiers. Ultimately, this will impact beneficiaries by placing a greater financial burden on those who find their medications are priced beyond the threshold. This would be particularly true for those taking a prescription that is reclassified from a lower tier to the specialty tier due to price increases.

CY 2011 Calendar Deadlines

The 2011 MA, MA-PD, Part D and Cost-Based Plan Calendar included with the Call Letter states that Part D plans may begin CY 2011 Marketing Activities on October 1, 2010. MAPRx is concerned that plans may begin marketing to beneficiaries on this date but are not required to have full plan information on their websites at this time. Oftentimes, plans do not have updated information for beneficiaries as they begin their marketing activities. This gap will result in beneficiaries being subject to marketing activities by Part D plan sponsors without the ability to obtain complete plan information necessary to make fully informed choices. MAPRx strongly encourages CMS to revise the 2011 calendar to require that sponsors post complete plan information online on the same day that marketing activities may commence.

MAPRx appreciates the opportunity to comment on the CY 2011 Draft Call Letter. Thank you for consideration of our input. 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.com.

Sincerely,

AIDS Action Council

National Osteoporosis Foundation

Alzheimer's Association

National Spinal Cord Injury

American Autoimmune Related
Diseases Association

RetireSafe

Arthritis Foundation

Spina Bifida Association of America

Breast Cancer Network of Strength

The Arc of the United States

Easter Seals

The ALS Association

Epilepsy Foundation

The Lupus Foundation of America

Men's Health Network

The National Council for Behavioral
Healthcare

Mental Health America

The National Psoriasis Foundation

National Alliance for Caregiving

United Cerebral Palsy

National Alliance on Mental Illness
(NAMI)

United Spinal Association

National Family Caregivers Association

National Grange of the Order of Patrons
of Husbandry

National Health Council

National Kidney Foundation

National Multiple Sclerosis Society

National Organization for Rare
Disorders (NORD)