



March 4, 2011

Dr. Donald Berwick
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Dr. Berwick:

MAPRx brings together beneficiary, patient advocacy, 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 the Medicare prescription drug benefit (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 Draft 2012 Medicare Call Letter regarding proposed actions related to the Part D program.

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

- Improved beneficiary protections;
- Specialty Tier guidance, including the threshold for inclusion on this tier and the inclusion of data for newly approved drugs;
- Co-pay thresholds;
- Automatic disenrollment from Special Needs Plans;
- Reassignment of Low-Income Subsidy recipients;
- Proposed plan rating criteria; and
- Approval of six-tier formularies.

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 (antineoplastics, immune suppressants,

anti-retrovirals, anti-convulsants, antidepressants, and antipsychotics) as the Secretary develops and issues new criteria as directed under the Affordable Care Act. 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. Furthermore, medication utilization management requirements, such as a “fail first” policy requiring beneficiaries to try less expensive drugs before obtaining a prescribed drug, prior authorization, or dosage restrictions, for drugs within the six protected classes are being used with increasing frequency by Part D plans. MAPRx urges CMS to undertake vigilant oversight of such policies to strictly limit their burdensome impact on beneficiaries. These utilization management tools directly impede the patient-doctor relationship by denying the beneficiary access to their physician’s recommended course of treatment. This may ultimately have the effect of worsening health outcomes by delaying access to needed medication, which has major cost implications for the beneficiary and Medicare due to avoidable hospitalizations and emergency room or doctor’s visits. MAPRx strongly condemns practices that negatively affect beneficiaries by hindering their access to the most appropriate therapies for their condition(s) and asks CMS to strictly monitor use of such techniques.

Second, MAPRx remains concerned about the issue of increasingly burdensome cost-sharing amounts 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. As noted above, CMS will again accept formularies with six tiers for Calendar Year (CY) 2012; meaning plans may have additional high-cost tiers in addition to the specialty tier. The increasingly common mix of copayments and coinsurance is particularly noteworthy in this respect as coinsurance 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.

Improved Beneficiary Protections

MAPRx appreciates the steps CMS has taken and continues to take to improve the Part D program for beneficiaries. Specifically, we are pleased to see that CMS continues efforts to ensure that plans have meaningful differences and eliminate duplicative plans that can easily confuse Part D enrollees. Ongoing enforcement of this requirement will ensure that beneficiaries have an easier time selecting a plan that best meets their needs. Additional steps to oversee plans, such as requiring plans with less than 3-star ratings to take corrective action and demanding documentation from all plans demonstrating that their transition plans are implemented correctly and that beneficiaries are receiving transition policies, are also greatly appreciated.

Similarly, MAPRx supports CMS’ attempts to standardize tier labeling and hierarchy among plans, believing that this will provide greater clarity to beneficiaries and improve their ability to select the most appropriate plan. This sort of oversight will continue to improve the Part D program by eliminating practices that could have a negative impact on beneficiaries.

Specialty Tier Guidance

The Draft Call Letter notes that the threshold drug price for inclusion on a specialty tier will remain at \$600 for CY 2012. MAPRx is both concerned and puzzled by this. This will be the fifth year in which the threshold remains at \$600 despite significant increases in drug prices over the same period. Even if accounting only for inflation, as opposed to specific pharmaceutical price increases, one would expect some rise in the threshold for inclusion on the specialty tier. It is particularly surprising that CMS would opt to retain the \$600 minimum after the release of the GAO study “Medicare Part D: Spending, Beneficiary Cost-sharing and Cost-Containment Efforts for High Cost Drugs Eligible for a Specialty Tier” (GAO-10-242) in January 2010 that found the median price of drugs included in specialty tiers, based on 2007 data, was \$1100 per month. This alone suggests the need to increase the threshold to reflect the higher price point for drugs in general and for high cost drugs and biologics in particular.

CMS, in the draft Call Letter, expresses concern about possible discriminatory cost-sharing by plans yet ignores this issue in relation to the specialty tier, where it would likely be most prevalent and effective due to the high costs of included medications. This is yet another reason for CMS to reevaluate the low threshold for inclusion on this plan formulary tier. In addition, MAPRx asks that the final call letter clearly address the methodology used to determine the cost threshold for the specialty tier in order for plans and beneficiaries to have a better understanding of exactly how this amount is determined.

With biologics likely to become an ever-increasing share of the medication market, it is imperative that CMS establish a realistic threshold for inclusion on the specialty tier. Otherwise, a growing number of medications will become eligible for this tier and its higher cost-sharing requirements due to the combined factors of drug price increases and newly available biologics. This would have the effect of placing further financial burdens on Part D beneficiaries, many of whom are on fixed income and simply cannot afford dramatic increases in out-of-pocket expenses. It would be a tragedy if more and more seniors and people with disabilities were unable to afford their medications and suffered worse health outcomes due to something as simple as an unrealistically low specialty tier threshold.

CMS notes in the Call Letter that specialty tier approval is dependent on plans presenting claims data showing that the majority of fills of included drugs exceed the CMS-established threshold. It adds that newly approved drugs are exempt due to limited or absent data. However, the Call Letter fails to provide guidance on when CMS expects plans to submit such data on newly approved drugs in order to evaluate their inclusion on plan formulary specialty tiers. MAPRx asks that CMS, in the final Call Letter, provide specific guidance on how long a plan has to submit claims data after it begins coverage of a new drug. Such guidance will prevent plans from inappropriately placing new drugs on the specialty tier and protect beneficiaries from high cost-sharing that might not otherwise be allowed. In making this request, MAPRx would note that we urge CMS not

to wait until the following year to begin evaluating claims data for newly approved drugs. Rather, we ask that CMS set a specific, limited period after which it will determine if a new drug may be placed on the specialty tier.

Finally, MAPRx continues to ask that CMS establish an appeals/exception process for drugs included on the specialty tier. Though not addressed in the draft Call Letter, this issue remains exceptionally important for beneficiaries with conditions that have limited treatment options, all of which are included on the specialty tier. For all other plan formulary tiers, beneficiaries may file an appeal for a drug to be placed on a lower cost-sharing tier if the medication is the only therapy available to them. Specialty tier drugs are the sole exception to this, despite these drugs often having the most burdensome cost-sharing requirements simply because they ARE on the specialty tier. There is no justification for the lack of an appeals process in these cases. MAPRx respectfully asks CMS to reconsider this policy and implement an appeals/exception process immediately.

Co-pay Threshold

CMS notes that plan sponsors can expect the agency to establish co-pay thresholds for each formulary tier that are reasonably consistent with those set for the 2011 plan year. The draft Call Letter notes the thresholds established for tiers 1, 2 and 3 are used to evaluate plans for discriminatory cost-sharing.

However, CMS fails to provide specific dollar amount thresholds regardless of the cost-sharing mechanism for tiers 4-6 despite stating in the draft Call Letter that it will accept six-tier plan formularies. The absence of thresholds for each of these tiers is alarming to MAPRx since these tend to be the high cost-sharing tiers and the tiers plans would likely utilize to engage in discriminatory practices. Without an established threshold for each accepted tier, it will be impossible to determine with certainty whether a plan is engaging in such practices. It will also be difficult for CMS to take corrective action against any plan that does use tiers 4-6 in a discriminatory manner since plans will be able to legitimately claim that they lacked any guidance from CMS on acceptable thresholds.

Therefore, MAPRx asks that CMS provide plans with guidelines on the acceptable cost-sharing threshold amounts for ALL tiers that a plan may seek to include on its formulary in order to provide clarity to the plan and beneficiaries.

Automatic Disenrollment from Special Needs Plans

CMS states in the draft Call Letter that, beginning in 2012, Special Needs Plans (SNPs) will be required to disenroll individuals who do not meet the targeted SNP criteria, such as having a chronic condition as specified by CMS. Plans are required to begin disenrolling such people by January 1, 2012 if the individuals do not voluntarily select another plan. CMS further notes that Medicare Advantage Organizations must notify enrollees on or before October 1, 2011, of the pending disenrollment and need to select another plan.

MAPRx understands the goal of this policy but asks that CMS provide plans with strict guidance on precisely how beneficiaries at risk of disenrollment are notified. It is

imperative that beneficiaries receive multiple notifications in simple, everyday language that clearly explains the situation and how to select another plan. A single communication to the beneficiary would be inadequate. Such communication must be provided in the best way to reach the beneficiary or caregiver, taking into account potential language issues and cultural considerations. Plans must receive instructions on how to provide notification in order to minimize beneficiary confusion and disruption.

Reassignment of Low Income Subsidy Recipients

MAPRx deeply appreciates the codification in the Affordable Care Act (ACA) of the de minimis policy whereby Low-Income Subsidy (LIS) recipients will no longer be automatically reassigned from a plan with premiums that exceed the LIS benchmark if the plan agrees to waive a part of the premium. This policy favors beneficiaries by limiting annual reassignments that often confuse beneficiaries and may affect any provider relationships that they have established under their existing plan.

In 2010, CMS noted that it was considering using “intelligent reassignment” when moving LIS beneficiaries from one plan to another. Under this policy, beneficiaries would be assigned to a plan that is best suited to their needs based on the beneficiary’s prescription drug regimen and the plan’s formulary design. At the time, MAPRx submitted comments to CMS strongly endorsing adoption of this policy. To date, CMS has yet to implement intelligent reassignment, despite its potential benefits to beneficiaries and plans. MAPRx continues to support adoption of this policy and asks that CMS institute this change at the earliest possible date.

Proposed Plan Rating Criteria

In the draft Call Letter, CMS asks for feedback on proposed evaluation criteria for MA and PDP plan ratings in 2012. Among the suggested additions that would specifically affect Part D plans are voluntary disenrollment rates, appropriate implementation of Part D transition processes to ensure continuity of care for beneficiaries, and medication adherence. CMS also notes that it is examining several possible enhancements for the 2012 Part D star ratings, such as providing greater weight to clinical outcomes and lesser weight to process issues and reducing ratings for contracts with serious compliance issues. In 2013, CMS proposes to add criteria such as grievances and medication therapy management measures.

MAPRx strongly supports all of these efforts to ensure more stringent evaluation of plans based on beneficiary health outcomes and satisfaction. The proposed changes mentioned above are essential determinants of whether or not plans are truly working for Part D beneficiaries and are therefore critical enhancements to the evaluation of all Part D plans. Once such criteria are added to the Plan Rating evaluations, it will be essential to present this information to beneficiaries in clear, concise language that enables them to better identify plans scoring highest on these critical points and, in conjunction with other key factors such as formulary design and cost-sharing requirements, are therefore deserving of consideration for enrollment.

Beneficiary advocates have repeatedly requested that SNPs be required to provide prospective and enrollees with a copy of their Model of Care. We request again that the Call Letter require SNPs to make their Model of Care available. Given how much the plans cost, and given that some SNPs do not really provide a benefit package that is "special," potential and current enrollees should have this information so they know what special services the plans say they will provide and the plans can be held accountable. In addition, it is difficult, if not impossible, to measure the quality of a SNP if the Model of Care is unknown. As noted at the recent MedPAC meeting, there is too little information about the SNPs or their Models of Care for duals or chronic conditions to ascertain the quality of care they are providing to their enrollees. The need for the Models of Care is even more important given the proposal to add SNP-specific measures to the plan ratings for 2012 and 2013.

Tier Labeling and Hierarchy

The CY 2012 Call Letter states that CMS will only allow a six-tier formulary if the sixth tier is an excluded- drug- only tier or a tier that provides a meaningful benefit offering. Examples of a meaningful benefit include a \$0 vaccine-only tier, a low or \$0 cost-sharing tier for special needs plans (SNP) targeting specific conditions, or an injectable drug tier with cost-sharing that is at or below the cost-sharing for specialty tier drugs in the other five tiers.

MAPRx is pleased with CMS' efforts to carefully review and scrutinize plan offerings with a large number of drug tiers. We acknowledge and understand that CMS' policy affords plan sponsors who offer multiple benefits flexibility to create unique, distinguishing formularies. We are concerned, however, that plan sponsors who offer only one drug plan are using this policy to their advantage and unnecessarily creating multiple drug tiers. This leads to beneficiary confusion when attempting to understand whether the formulary covers their drugs and the applicable cost-sharing amounts. MAPRx requests that CMS amend this policy by making it applicable to plan sponsors who intend to offer multiple drug benefits.

In addition, MAPRx asks that CMS provide further guidance on exactly what products/services are subject to inclusion on the sixth tier. As noted previously, MAPRx is extremely concerned with the dramatic increases in cost-sharing that subject Part D beneficiaries to ever-increasing out- of- pocket expenses that few of them can afford. Therefore, we are alarmed at that possibility that plan sponsors may use CMS' acceptance of six-tier formularies to institute yet another high cost-sharing tier in addition to the specialty tier and/or multiple non-preferred brand or non-preferred generic tiers. Such an abuse of this policy would cause not only greater confusion due to the proliferation of multiple tiers and varying cost-sharing requirements – making plan-to-plan comparisons nearly impossible for beneficiaries – but could become an additional financial hardship and barrier to effective, necessary treatment. MAPRx urges CMS to engage in strict oversight of any and all plans that submit five- or six-tier formularies to ensure that this structure does not become a way to push costs on to beneficiaries or to discriminate against those beneficiaries with serious chronic conditions.

MAPRx appreciates the opportunity to comment on the Draft 2012 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.org.

Sincerely,

The ALS Association

Alzheimer's Association

American Autoimmune Related Diseases Association, Inc.

American Society of Consultant Pharmacists

Arthritis Foundation

Cystic Fibrosis Foundation

Easter Seals

Epilepsy Foundation

Hemophilia Federation of America

Lupus Foundation of America

Men's Health Network

Mental Health America

National Alliance on Mental Illness (NAMI)

National Council for Community Behavioral Healthcare

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)

National Osteoporosis Foundation

The National Psoriasis Foundation

National Spinal Cord Injury Association

Parkinson's Action Network

RetireSafe

Spina Bifida Association

United Spinal Association