



May 14, 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D for essential medications, the MAPRx Coalition appreciates this opportunity to submit comments in response to the Draft Guidance for implementing the Medicare Coverage Gap Discount Program (hereafter referred to as the Discount Program).

Specifically, MAPRx would like to address the following issues raised in the Draft Guidance:

- Notice to beneficiaries on the following issues:
  - Discount status of drugs on 2011 plan formularies;
  - Advance notice regarding drugs that will not be covered in 2012 due to lack of a manufacturer agreement;
  - Clarity regarding what beneficiaries will actually have to pay at point of sale (POS);
  - Changes in negotiated price; and
  - Eligibility for the discount.
- Retroactive application of the 50% discount
- Health exception for excluded drugs

### **Notice to Beneficiaries**

Changes enacted under the Patient Protection and Affordable Care Act (PPACA) and Health Care and Education Reconciliation Act of 2010 require that brand name drugs covered under Medicare Part D be subject to a manufacturer discount of 50% for those beneficiaries in the coverage gap. Drugs from manufacturers who do not sign agreements to offer the discount will no longer be covered under Part D. The legislation grants CMS

the authority to allow coverage for drugs not subject to such agreements under two scenarios:

- The drug is determined to be essential to the health of Part D beneficiaries; or
- There are extenuating circumstances for 2011.

Draft guidance states that CMS does consider there to be extenuating circumstances for 2011 “due to conflict between the timing of 2011 formulary submissions and the signing of manufacturer discount agreements.” This conflict, according to the guidance, means that some drugs offered under Part D plans in 2011 may not be subject to the 50% discount unless “all manufacturers of Part D drugs enter into agreements for 2011 by our deadline in 2010.”

While the MAPRx Coalition appreciates the challenges of implementing the discount, we are greatly concerned about the potential confusion to beneficiaries. The drug discount has received substantial coverage in the press and is one of the health reform bill’s best-known provisions. We suspect most beneficiaries are aware of this change and expect it to take effect in 2011. Because the discount directly affects those with the highest out of pocket costs, those Medicare enrollees who stand to benefit from the discount eagerly await the financial relief it promises. If the discount is not fully implemented in 2011, beneficiaries will find it extremely challenging to determine which of their medications are subject to the discount and plan accordingly. As a result, they will continue to bear the burden of increasing cost sharing at a time when many of them were expecting relief.

**MAPRx urges CMS to do all it can to ensure that the discount is fully implemented in 2011 in order to guarantee that enrollees get the benefit of this program.** If that is not possible, we cannot stress strongly enough the need for clear, timely and repeated communication with enrollees to explain why all drugs are not covered and to notify them if they are taking medication that is not subject to the discount. This communication will benefit all involved – beneficiaries, CMS, plans, pharmacists, providers – by minimizing confusion and allowing for adequate planning.

Beginning in 2010, Part D plans must notify beneficiaries if a drug is no longer covered due to the manufacturer not agreeing to provide the discount. There is no requirement for the plan to supply a transition refill. Again, MAPRx is concerned about plan enrollees receiving clear and timely notice of such changes and the problems that could arise if this is not achieved.

**For plan year 2012 and beyond, CMS must require plans to provide significant advance notice of coverage changes for any and all drugs due to lack of a manufacturer agreement to provide a discount.** Should enrollees not receive such notice well in advance of the change, they will not have time to consult with their providers to make alternate treatment decisions, possibly resulting in treatment disruption that will produce negative health outcomes and possibly greater costs for both the beneficiary and the Medicare program. Therefore, this requirement must be not only enacted but vigilantly enforced for the benefit of enrollees.

The requirement to notify beneficiaries of changes in drug coverage due to absence of a manufacturer agreement raises the question of how often manufacturers will be required to sign such agreements. Will agreements be annual or will they cover multiple years?

If manufacturers are required to sign agreements annually, MAPRx requests that CMS set the deadline for agreements prior to the submission of plan formularies. Release of formularies prior to a deadline for manufacturer agreement again presents an extremely challenging situation for enrollees who may be given short notice that their medications are no longer covered under Part D. **Therefore, we ask that CMS establish an orderly process whereby plan formularies are not released until manufacturer agreements are signed or rejected in order to ensure that enrollees experience the minimum amount of confusion and receive the maximum amount of notice.**

As noted previously, the 50% discount has received widespread publicity through media coverage. Many, if not most, beneficiaries would therefore assume that they will be paying only 50% of the negotiated drug price once they reach the coverage gap. For example, they would likely expect to pay \$50 for a drug with a negotiated price of \$100. However, enrollees may not be aware that they will continue to be responsible for paying the dispensing fee in addition to the actual drug costs. **Therefore, MAPRx asks the CMS provide enrollees with a clear, concise, “plain-English” explanation of precisely what costs they will face in the coverage gap once the discount program is operational in 2011.**

Because the discount has received significant publicity and is expected by enrollees, it will also be vital to ensure that all Part D plan participants have a clear understanding of their plan’s formulary and are aware of which drugs will and will not be subject to the discount if they reach the coverage gap. Beneficiaries must be informed prior to the start of each plan year that certain drugs are covered under the “essential to health” exception but are not part of a manufacturer discount agreement. Similarly, beneficiaries should be reminded before the start of each coverage year that generic drugs – other than authorized generics – will not be part of the discount program. As part of this reminder, the difference between generics and authorized generics must be explained in the clearest, simplest, most understandable terms possible in order for beneficiaries to have a true understanding. **MAPRx urges in the strongest possible terms that CMS require Part D sponsors to provide significant advance notification to plan enrollees of the approved formulary for the coming year, including which drugs will and will not be covered under the discount program and an explanation of why certain drugs are not included in the 50% discount program.** Providing this advance notice will allow beneficiaries to consult with their physician(s) and other providers regarding treatment with full knowledge of what costs they are likely to face depending upon the drug therapy they opt for. Without such clear notice, enrollees may face crushingly high unexpected costs that they simply cannot afford and/or treatment disruption if they stop taking medication or must scramble to find an alternate drug therapy.

Per CMS draft guidance, the discount will be calculated and provided to the beneficiary at point of sale. Furthermore, the draft guidance notes that CMS is revising the model Part D EOB to “highlight the applicable discounts that are provided by manufacturers on coverage gap claims.” MAPRx applauds this effort to ensure beneficiaries have a thorough understanding of the costs associated with their prescription drugs. **However, MAPRx also asks that CMS consider implementing a requirement for enrollees to receive notice at point of sale providing a detailed breakdown of what they paid for**

**a drug, what the negotiated price is and what the manufacturer paid through the discount program.** This will ensure that enrollees have a fuller understanding of how the discount program is working and allow for them to more easily track their drug spending. It will also be useful in situations where only part of a drug's cost falls under the coverage gap or the drug is a compound, meaning in both cases that only part of the drug's cost is subject to the discount.

Even with the 50% discount, the cost of prescription drugs remains a concern for beneficiaries and MAPRx, particularly for those with the highest drug costs such as enrollees who require treatments placed on the specialty tiers. With the introduction of the discount, MAPRx is concerned that, depending on how long contracts for negotiated prices last, manufacturers could change prices during a plan year in order to minimize the effect of the discount. Enrollees would then be subject to large cost increases unexpectedly. **If this scenario is possible under any circumstances at all, MAPRx asks that CMS institute policies to protect enrollees from large price increases that would impose a significant financial burden due to greatly increased cost sharing.** At a minimum, CMS should require plans and/or the manufacturer to provide significant advance notice to enrollees of the impending price change in order to allow for decisions about alternate treatments and/or revised financial planning.

**Finally, MAPRx asks that CMS provide plans and beneficiaries with information presented in clear, non-technical language that explains which beneficiaries are eligible and which are not eligible for the discount upon reaching the coverage gap.** This notice would have the positive effect of ensuring that the discount program implementation runs more smoothly by minimizing initial confusion over who should be receiving the discount at point of sale. Given that the draft guidance proposes no retroactive application of the discount even upon successful appeal of denials, such clarity would be highly beneficial to all involved.

### **Health Exceptions for Excluded Drugs**

CMS may allow coverage of brand name drugs not subject to a manufacturer's agreement to provide the discount if it determines that a medication is essential to the health of Part D enrollees. The draft guidance states that "CMS will inform Part D sponsors if any Part D drug not covered by a manufacturer agreement has been determined to be essential for the health of Part D enrollees and exempt from the manufacturer agreement requirement."

**Although MAPRx supports the CMS' ability to extend coverage to drugs that are essential to the health of enrollees, we ask that CMS provide greater disclosure/explanation of how such a decision will be made and who at CMS will be responsible for making this determination. MAPRx also requests clarity on whether this decision will be made as a broad exception or on a case-by-case basis based for specific enrollees.**

MAPRx is also concerned about the possible lack of coverage for a new, highly effective drug for which the manufacturer refuses to offer the discount. Although such a drug could provide exceptional health benefits to enrollees, particularly those with few

treatment options, it may not be subject to coverage due to not meeting the requirement of being “essential to the health” of enrollees. **Therefore, MAPRx asks that the Secretary of Health and Human Services have the authority to rule that such a drug is a “miracle drug” to guarantee coverage for Part D enrollees.**

Drugs that CMS approves for coverage under this exception are likely to be the highest cost therapies available. Although it is vital that Part D enrollees have access to such drugs, the absence of the 50% discount means that beneficiaries who are in need of them will be subject to an onerous financial burden. This could preclude some beneficiaries from filling prescriptions and adhering to treatment, thereby resulting in negative health outcomes. **In order to ensure that beneficiaries who require such costly medications have access to them, MAPRx asks CMS to issue guidance notifying plans that drugs granted coverage under this process may not be placed on plan specialty tiers.** The specialty tiers place a significant cost-sharing burden on enrollees, often requiring coinsurance of up to 40%. **Prohibiting placement on the specialty tier of drugs granted coverage under the health exception would be an important step to protect beneficiaries by limiting the cost-sharing they would face for these critical drugs.**

### **Retroactive Application of the Discount**

The draft guidance calls for Part D sponsors to use the “date of dispensing” for determining the amount and providing the discount at the point of sale. It adds, “limiting this determination to the ‘date of dispensing’ eliminates the potential for retroactive changes in eligibility...for purposes of adjusting the discount. Thus, the status of the claim and beneficiary eligibility on the date of dispensing will be the sole basis for determination of eligibility of the discount and amount of the discount, even if later information retroactively changes effective eligibility back to the date of service.”

**MAPRx finds this policy extremely troubling and asks CMS to consider revisions to it. The lack of retroactive applicability of the discount is extremely problematic for those enrollees who undertake the process to appeal a denial.** Upon being denied the discount, an enrollee may pay a very high out of pocket cost for a drug and file an appeal. Under the draft guidance policy, the enrollee could win the appeal and have the denial overturned, but despite being in the coverage gap due to high drug costs, would not receive the 50% discount to which they should have been entitled.

**MAPRx asks that CMS change this policy and issue regulations stating that, should a beneficiary successfully overturn a denial on appeal, this decision would be applied as if it had happened at point of sale and the enrollee would receive the discount retroactively.**

MAPRx appreciates the opportunity to comment on the Medicare Coverage Gap Discount Program. 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](mailto:Marybeth@maprxinfo.org).

Sincerely,

Alzheimer's Association

American Autoimmune Related Diseases Association

Arthritis Foundation

Breast Cancer Network of Strength

Epilepsy Foundation

Lupus Foundation of America

Mental Health America

National Alliance on Mental Illness (NAMI)

National Council for 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 Psoriasis Foundation

National Spinal Cord Injury Association

Parkinson's Action Network

RetireSafe

United Spinal Association