



January 11, 2011

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

Dear Dr. Berwick:

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 Proposed Rule for changes to the Medicare Prescription Drug program (Part D) for Contract Year 2012.

Specifically, MAPRx would like to address the following issues raised in the Proposed Rule:

- The Appeals Process and Enrollee Complaints
- Drug Dispensing for Part D Beneficiaries in Long Term Care Facilities
- Authority to Deny Bids & Potential Additional Restrictions
- Compound Drug Policy

The Proposed Rule also addresses implementation of many components of the Affordable Care Act (ACA) related to Part D. MAPRx would like to note that we are supportive of the many proposed changes that will make the program easier for beneficiaries to understand and utilize, including the following:

- Voluntary *De Minimis* Policy allowing plans to waive a *de minimis* monthly premium for low-income subsidy (LIS) individuals enrolled in the plan and prohibition of reassignment of LIS individuals who are enrolled in such plans.

- The proposal to allow beneficiaries subject to the new Part D Income Related Monthly Adjustment a three-month grace period to pay arrearages before being disenrolled from their plan.
- Inclusion of costs paid for by the Indian Health Service or the AIDS Drug Assistance Program (ADAP) to count towards the annual Part D out-of-pocket limit.
- Restrictions on plan marketing activities, including the requirement for broker training and the termination of unlicensed brokers.
- Prohibiting repackaged versions of plans that were required to or opted to terminate participation in the Part D program.
- The proposal for Part D plans to provide enrollees with personalized information to enable them to compare utilization and out-of-pocket costs in the current plan year to projected costs in the upcoming plan year.
- The proposal to allow reinstatement in Part D plans for individuals who were involuntarily disenrolled for failure to pay plan premiums if the individual can demonstrate good cause for failure to pay.
- Closure of the Part D coverage gap.

Although MAPRx supports requirements that plan sponsors provide interpretations for beneficiaries who do not speak English or have limited proficiency with English, we are very concerned about the threshold included in the proposed rule. CMS would require Part D plans to offer translated marketing materials in any language spoken by more than 10% of the population in the plan's service area. However, the 10% limit seems rather arbitrary and would exclude many beneficiaries who speak a language that is less common in a particular area. It may also result in vast inconsistencies among plan areas, with beneficiaries in some service areas having access to translation services while those in other areas do not.

Therefore, MAPRx asks that CMS adopt a different standard for requiring plans to offer translated materials to beneficiaries. We ask that CMS set the threshold for such services at 5% of the population or 500 people in a service area, whichever is less. This will ensure that the maximum number of Part D plan enrollees who require language assistance will have access to it, enabling them to fully understand and utilize their plan benefits.

The Appeals Process and Enrollee Complaints

MAPRx strongly supports CMS' proposal to require all Part D plans to employ a single, uniform exceptions and appeals process. It is essential that the appeals process be as easy, clear and straightforward as possible in order for beneficiaries to effectively utilize it. Many Part D beneficiaries rely on specific medications to treat their conditions,

symptoms, and/or side effects and must have the ability to access the drugs prescribed in consultation with their doctor(s). A single, uniform appeals process will serve beneficiaries by providing consistency between plans, thereby minimizing any confusion when enrollees change plans or are reassigned. Furthermore, the requirement that plans accept such appeals both in written form and orally simplifies the process and enables more rapid resolution of an appeal – both of which will make the process work better for beneficiaries.

We would also like to express our endorsement of the ways in which CMS seeks to implement this process. CMS would require plans to:

- Use a standard form to request a determination. MAPRx would request that a standard form approved by CMS be written in the most plain language possible, free of any jargon or terms that might cause confusion among those attempting to utilize it. Completion and submission instructions must also be made absolutely clear. Similarly, we ask that the form be made brief by requiring needed information, including the prescribing doctor's name and contact information, in order to avoid burdening those who need immediate access to medically necessary medication.
- Establish a toll-free number specifically for requesting a determination. MAPRx asks that CMS also require plans to use every opportunity – beneficiary mailings, marketing materials, website, point of sale communications – to highlight this toll-free number in order to ensure that beneficiaries are aware of this option. Otherwise, it is likely the number would become one more listed in fine print on written communications or obscurely placed on a website. Beneficiaries must be made aware of this option to request immediate determination of an appeal. All such communication highlighting the toll-free number must also note the information that beneficiaries will be required to provide. Coverage determinations should not be delayed because beneficiaries lack the information required for plans to make a determination. Any such delays will not only frustrate plan enrollees but will ultimately worsen health outcomes if beneficiaries' treatment regimens are disrupted.
- Provide a secure website allowing for immediate determination. As with the standard form, it is essential that the information on each plan's website be as clear, simple and straightforward as possible. Many seniors are not overly proficient with the internet and should not have to struggle to find or comprehend information provided online by a plan. In addition, the design of the site – typeface, menu, etc – must be completed with the target audience in mind. This would mean larger fonts, a short & direct menu easily located on each page, and a very prominent "Help" feature.

In addition to providing a method for Part D plan enrollees to submit exception requests electronically, CMS must require that plans provide a similar method for enrollees' doctors to submit documentation in support of the request. In most situations, doctors or prescribers will need to submit supporting documentation and must have a way to do so electronically and in a manner that is easily

coordinated with the original exception request if submitted separately. It is critical that separate informational submissions by physicians NOT become an impediment to rapid determination of the exception request.

For all exception requests, whether submitted by telephone or electronically, it is essential that enrollees receive from the plan an email or letter documenting the receipt and date of the request. This will prevent any confusion about if and when requests were submitted and will ensure plans cannot claim to never have received the request.

MAPRx also urges CMS to require plans to provide language assistance (in the case of the toll-free line) or translated materials (for the standard form and the website) for beneficiaries who either do not speak English or have limited proficiency with the language. Without such a requirement, the appeals process could become essentially useless to these plan enrollees.

CMS also proposes requiring plans to provide to pharmacies a model point-of-sale notice to be given to plan enrollees when a prescription fill is denied. MAPRx supports this requirement, but asks that CMS go beyond requiring a “model” notice by directing plans to provide an individualized form explaining that the prescription has been denied and providing explicit information on all possible avenues for submission of an appeal. This will ensure that beneficiaries understand precisely the reason for denial, what their rights are and the process for obtaining a coverage determination. Without such a notice, the beneficiary will be burdened with the need to gather the necessary information, ultimately delaying final determination and access to needed medication.

Finally, CMS requires that medical compendia support off-label use of a specific drug to treat a condition and/or symptoms. When establishing a uniform appeals process, it will be necessary for enrollees and their physician(s) to have access to the accepted compendia in order to make the strongest case possible. MAPRx asks that CMS ensure that all beneficiaries have access to both the accepted medical compendia and assistance in understanding and utilizing information in the compendia to support the appeal. Given that there is no public access to the Compendia, we also ask that plans, at a minimum, be required to provide beneficiaries and their doctors a copy of the relevant section that the plan is citing to support denial of coverage.

In a related matter, CMS proposes to require plans to address all complaints received through the Complaint Tracking Module. Plans would have to include a link on their website to the complaint form found on the Medicare website. MAPRx encourages CMS to implement this rule, with the same stipulations requested above: obvious placement, ease of use, crystal clear language, and a design that makes it easy for elderly beneficiaries to utilize. Furthermore, we request that CMS specifically require plans to resolve complaints in a timely manner, perhaps by outlining a timeframe for resolution. If a plan cannot abide by the deadline, plans should be required to notify both the enrollee and CMS and provide specific reasons for the delay.

Drug Dispensing for Part D Beneficiaries in Long Term Care Facilities

In an effort to reduce waste, CMS proposes changes to the manner in which plans fill prescriptions for enrollees in long-term care (LTC) facilities. Plans would be required to initially dispense brand-name medications in a 7-day or less supply, with certain exceptions such as drugs that are difficult to dispense in this manner or are prescribed for acute illnesses.

The intertwined goals of reducing waste of prescription drugs and associated costs are understandable. However, MAPRx is concerned about this proposal insofar as it has the potential to affect beneficiaries. If this policy is instituted, it will be essential that it be implemented in such a way that no beneficiaries experience even the slightest interruption to the medically necessary treatment prescribed by their doctor(s). This must be taken into account when allowing for certain exceptions to the requirement, along with those examples cited above. CMS must be explicit with plans that any implementation policies that would result in treatment disruption are strictly prohibited under this requirement.

In the proposed rule, CMS notes that implementation of this proposal would likely lead to a change in copayment methodology for beneficiaries not eligible for the low-income subsidy. Similar to our concern with the potential for treatment interruption, MAPRx seeks to ensure that any copayment changes would in no way act as a greater financial burden for plan enrollees. Therefore, we ask CMS to require that plans take into account the possible effect of such changes on enrollees and, if implementing new copayments, confirm that they will not cause financial hardship. With many Part D beneficiaries already finding it a challenge to pay for needed prescriptions, this new regulation must not become another barrier to access.

In addition to ensuring that enrollees do not face additional financial burdens upon implementation of copayment changes, CMS must require plans to provide beneficiaries with a clear, easily understood explanation of the changes. This notice must be distributed to enrollees well in advance of implementation of such changes in order to minimize any possible confusion.

Along similar lines, CMS proposes changing the definition of “dispensing fee” to include costs associated with implementation of the 7-day or less fill policy. MAPRx is concerned that this re-definition may have a negative financial impact enrollees. Placing more cost burdens on Part D beneficiaries in an effort designed, at least in part, to reduce CMS’ costs is unacceptable. MAPRx asks that CMS closely examine the financial impact of any such changes upon beneficiaries and limit cost increases, if any, to a bare minimum.

Based on the text of the proposed rule, MAPRx assumes that the new drug dispensing regulations would not apply to those pharmacies serving beneficiaries receiving care in home and community-based settings. We ask that CMS make this explicitly clear when issuing the final rule in order to ensure clarity among providers, pharmacies and beneficiaries as to precisely who will and will not be affected.

Authority to Deny Bids

CMS seeks to codify the authority of the Secretary of Health and Human Services to deny Part D plan bids, supported by provisions of the ACA that require plan sponsors to offer high quality plans that have meaningful differences. Furthermore, CMS proposes imposing additional restrictions, such as allowing the Secretary to impose premium increase thresholds and limit the number of plans that may be offered in a service area.

MAPRx views the ability to deny plan bids, along with the requirement that plans be high quality and have meaningful differences, to be extremely helpful to beneficiaries. MAPRx applauds CMS for implementing such policies that will benefit program participants. These criteria will minimize possible confusion among beneficiaries as they navigate the Part D program by guaranteeing that they are not overwhelmed with plans from the same sponsor that fail to offer a truly different benefit. We hope this will reduce the risk of beneficiaries enrolling in plans that do not best serve their needs by making comparisons easier based on individual drug utilization and plan benefits.

Regarding the possible implementation of additional restrictions, MAPRx supports allowing the Secretary to establish premium increase thresholds. This policy would guarantee some insulation from financial shocks to beneficiaries by ensuring they do not experience excessive premium increases. With many beneficiaries having faced double-digit rises in premiums in recent years, a policy that would stabilize such cost increases could be a substantial benefit to plan participants.

Nevertheless, if the Secretary is granted authority to cap the number of plans in a service area, such caps must be implemented to ensure adequate beneficiary choice. MAPRx seeks to ensure that Part D beneficiaries have access to a variety of high quality plans in order to enroll in the one that best serves their needs. As noted above, MAPRx supports requirements for plans to have meaningful differences in order to minimize beneficiary confusion when sorting through plan options. However, a cap could potentially limit the number of high quality plans in a service area if enforced too narrowly. Should the Secretary be given such authority, it must be done with the clear understanding that each service area will still have a variety of plans to address the divergent needs of Part D participants. This authority should not be utilized to set hard caps with a small number of restrictive plans based on the notion of cost saving.

Compound Drug Policy

In the proposed rule, CMS seeks to codify current guidance that only compound drugs containing at least one component that qualifies as a Part D drug may be covered under Part D. CMS would allow plan sponsors to cover Part D drug components of compounds even if the compound itself does not qualify for Part D coverage. However, any compound components that do not independently meet the requirement of a Part D drug would not be eligible for coverage under Part D. CMS proposes that flat copayments for compounded Part D drugs represent the copay of the tier of the most expensive Part D

ingredient; for coinsurance, such amounts must be applied to all Part D ingredients of the Part D compound. Additionally, any compound that contains a component covered under Medicare Part B would be covered under Part B and no components of the compound would be eligible for coverage under Part D.

MAPRx is very concerned about the possibility of significant enrollee confusion related to implementation of this policy. Coverage of certain drug components and varying payment structures depending on copayments and coinsurance would be challenging for anyone to understand. For beneficiaries with cognitive challenges or disabilities, such rules could prove incomprehensible.

Another major concern is the policy's financial impact on beneficiaries. If some parts of a compound are covered but others are not or compound components are covered under varying copayment and coinsurance rules, it will be nearly impossible for enrollees to anticipate their out-of-pocket costs for compounded drugs. The policy has the potential to impose substantial financial burdens on enrollees who require compounded drugs, particularly those using high cost specialty medications. The financial impact could also come as a shock to beneficiaries due to the challenge of fully understanding the coverage policies related to compound drugs. As a result, Part D participants may find themselves unable to afford compound drugs deemed medically necessary by their doctor, resulting in deteriorating health.

MAPRx urges CMS – in the strongest possible terms – to consider these factors as it moves ahead with implementation of this policy. We ask that CMS and/or Part D plan sponsors be required to provide a simple, clearly-worded explanation of the policy to all Part D plan participants as well as providing access to information both online and by phone. Whether communicated in writing, online or by phone, it will also be essential that such information be available in translation for those beneficiaries who do not speak English or have limited English proficiency. Any explanation of the policy must also explicitly delineate how costs will be determined and the potential financial impact on beneficiaries. Again, assistance must be made available for those who have difficulty grasping the financial details and impact of the policy.

The specific regulation related to compounds containing a component covered under Part B also has the potential to negatively impact beneficiaries. The coverage policy for such compounds must also be made exceptionally clear to all beneficiaries, primarily to insulate them from the financial impact of obtaining a drug that will not be covered under Part D but would be covered under Part B. When obtaining a compound drug that includes a Part B-covered component, beneficiaries should be made aware of this as well as the fact that Part D will not cover the compound under any circumstances. This information should also instruct the beneficiary on the proper procedure to ensure that the claim is submitted under Part B and therefore covered.

MAPRx cannot express strongly enough how important it will be to provide beneficiaries as well as pharmacists with clear, concise explanations of the compound drug policy. Otherwise, beneficiaries and pharmacists face possible misunderstandings/confusion around what is and is not covered, causing possible treatment interruptions and financial hardship for beneficiaries. CMS notes in the proposed rule that it is considering whether

the financial impact of unreimbursed components may deter pharmacies from providing compound services. Providing the sort of explicit instructions requested by MAPRx will significantly minimize any financial impact on both pharmacies and beneficiaries and make the policy much easier to implement on all levels.

MAPRx appreciates the opportunity to comment on the Proposed Rule. 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 Association of Consultant
Pharmacists

The Arc of the United States

Arthritis Foundation

Easter Seals

Epilepsy Foundation

Lupus Foundation of America

Men's Health Network

Mental Health America

National Alliance for Caregiving

National Alliance on Mental Illness

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

National Psoriasis Foundation

RetireSafe

United Cerebral Palsy