



MAPRx Coalition – 2010 Priority Issues

MAPRx, a coalition of patient, family caregiver and health professional organizations representing millions of Americans, was formed in response to the passage of the Medicare Modernization Act (MMA). MAPRx is committed to ensuring that people with chronic conditions and disabilities have access to necessary, affordable prescription drugs, whether through Medicare Part D or private insurance. Our mission is to guarantee that beneficiaries, in addition to having access to prescription drugs, receive accurate, timely information as they make insurance coverage and treatment decisions.

For 2010, MAPRx has identified six policy priorities regarding Medicare Part D:

- Cost-Shifting Financial Burden on Patients
- Medication Utilization Management
- Off-Label Use of Prescription Drugs
- Six Protected Classes
- Two-Year Eligibility Wait Period
- Comparative Effectiveness Research

Position Statement on the 2010 MAPRx Priority Issues:

More than 44% of Medicare beneficiaries live with three or more chronic conditions and 29% have a cognitive or mental impairment, according to The Kaiser Foundation's report *Medicare: A Primer 2010*. The Medicare Part D program has largely been a success but for the millions of beneficiaries with chronic illnesses and/or disabilities, access to necessary medication is increasingly more challenging, more expensive and less transparent than for the rest of the Medicare population.

Increased Cost-Shifting Imposes A Financial Burden on Patients

Plan formularies place drugs in different tiers, with the most expensive put in non-preferred brand and, increasingly, specialty tiers. Drugs costing \$600 per month or more may be included on the specialty tier, with beneficiaries typically paying a percentage of the drug's cost rather than a flat co-pay. Co-insurance for drugs on the specialty tier is generally 33% though some plans have charged as much as 40%. While we recognize that CMS has given plans flexibility to adjust cost-sharing rates to equal a 25% actuarial value, we are concerned that plans have utilized that flexibility to impose abusive cost-shifting onto beneficiaries. We ask CMS, in the interest of alleviating the crushing financial burden that this can place on beneficiaries, to consider placing limits on how plans may interpret this provision.

In 2007, specialty tier medications were used by 4.4% (over 2 million) beneficiaries with expenditures that accounted for about 10% of the cost of all drugs under Part D. MAPRx is concerned about the growing use of specialty tiers by Part D plans and the increasing number of drugs added to these tiers. This places a heavy financial burden on beneficiaries and limits access, with devastating consequences. A 2010 study by Milliman, Inc. looking at claims for oral chemotherapy and non-hormonal drugs costing more than \$1500 per month found that patients take fewer life-saving medications as the cost increases. Furthermore, unlike with other tiers, beneficiaries may not request an exemption to have a drug placed on a lower cost tier when no alternative therapy is available. Individuals living with cancer, multiple sclerosis, arthritis and other conditions often take several medications and must pay thousands of dollars out of pocket before reaching catastrophic coverage. The financial burden of specialty tiers not only lead to poorer health outcomes but greater long-term health expenditures due to the need for higher cost care to treat the consequences of non-adherence to treatment.

However, increased cost-shifting to beneficiaries is not limited to drugs on the specialty tiers. Coinsurance is increasingly common on plan formularies' non-preferred brand tiers as well. In fact, the coinsurance rates imposed on these tiers often exceed the rates on the specialty tiers, in some cases reaching up to 60% of a drug's cost. As with the specialty tier requirements, the financial burdens associated with this sort of cost-shifting can have severely negative health and financial impacts on beneficiaries who find themselves either struggling to pay for medication or simply unable to pay for necessary treatment. Furthermore, plans' use of such exorbitant cost-sharing requirements may ultimately be discriminatory in that they will have the effect of driving away those with more significant health challenges while leaving plans to cover a relatively healthy population, thereby saving money.

In addition, plans' mix of co-payments and coinsurance cause significant confusion, especially for those on multiple and/or expensive medications who try to compare plans. Greater clarity on this issue is needed to enable beneficiaries to make a determination of which Part D plan best meets their needs.

Stop Abusive Medication Utilization Management by Part D Plans

An increasing number of Part D plans will, in 2010, employ medication utilization management tools such as medication substitution, step therapy or quantity limits. MAPRx is extremely concerned about use of these techniques, which have the potential for significant negative impact on patient health.

Part D plans may mandate that a beneficiary be prescribed a different, usually less expensive, drug in the same class or a different formulation (brand to generic or generic to generic). However, substitution, for any reason, can cause problems for patients and should not be mandated by anyone other than a medical provider and with the patient's informed consent. There should also be provisions in place to ensure access to and coverage of specific, physician-prescribed therapy when the physician has determined its need. Switching a patient from an effective medication to one with a different chemical

makeup could result in medical complications with dire health consequences. Part D plans should implement a process by which a physician can ensure their patient receives needed therapies.

Another concern related to substitution is biologics. Biologics are made from living cells and are more complex to replicate. To minimize potential adverse health outcomes, automatic substitution of biologics without consent of the treating physician should not be permitted.

The most frequent utilization tool is step therapy: a plan requires beneficiaries to first try a similar drug or biologic other than that prescribed for them and risk an adverse reaction or otherwise demonstrate that it is therapeutically ineffective before they will cover the drug(s) originally prescribed by their physician. This allows insurers to override a health care provider's practice of medicine by forcing utilization of medications or therapies that may be inappropriate. There is also a lack of information and transparency since many patients are unaware of plans' utilization management tools, the importance of being aware of plan changes or the right to appeal.

Dose restrictions or quantity limits are additional tools employed by Part D plans. Plans may limit the number of doses a beneficiary is allowed to obtain or limit the quantity of drugs covered over a period of time, regardless of a physician's prescription. The appeal process can be time-consuming, resulting in adverse health consequences, and places an unnecessary burden on patients and physicians to justify treatment decisions.

MAPRx calls for an end to abusive or harmful medication utilization management tools and a guarantee of clear, relevant patient information on a plan's use of such tools prior to enrollment.

Modify the Blanket Exclusion for Off-Label Use of Prescription Drugs

Medicare regulations exclude payment for drugs under Part D that are prescribed for uses other than those approved by the Food and Drug Administration (FDA) or for a use not cited in specific medical compendia. Exclusive reliance on FDA indications and a limited number of compendia may prevent access to medically necessary, life-sustaining prescription medications. Current standards for coverage of drugs, used off-label, under Part D are inconsistent with generally accepted medical guidelines, including Medicare Part B regulations, many Medicaid programs and private insurance rules, which allow consideration of evidence of effectiveness in peer-reviewed literature. Medicare Part D plans should provide access for ALL medically accepted uses for drugs – including those cited in peer review literature. This policy change would have many benefits: possibly preventing the need for costlier acute care such as hospitalizations and preserving the doctor-patient relationship, which allows physicians and patients to determine the best course of treatment.

Creating a policy that allows for case-by-case appeal and analysis of the appropriateness of off-label use of drugs under Part D will help improve the quality of life for populations in need of greater treatment options.

Ensure Continued Access to All Drugs in the Six Protected Classes

Guidance from the Center for Medicare and Medicaid Services (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. MAPRx supported the legislation intended to strengthen the current CMS guidelines regarding plan coverage of the six protected classes and continues to advocate for this provision.

CMS has proposed changes to the regulations regarding establishment of protected classes, clarification of accepted uses of utilization management, and an exception to the requirement to cover “all” drugs in a class. MAPRx seeks to ensure that any changes do not result in the weakening of the protected classes or additional barriers to needed medications.

Eliminate the Two-Year Wait 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. More than 1.8 million Americans are currently subjected to the waiting period. Among those waiting for Medicare coverage, two-thirds live below 200% of the federal poverty level and more than half are over age 50.

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.

Prohibit Use of Comparative Effectiveness Research in Coverage or Reimbursement

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.