



**STATEMENT OF THE NATIONAL ALLIANCE ON MENTAL ILLNESS TO THE
MEDICARE PAYMENT ADVISORY COMMISSION ON PROPOSALS TO REFORM
COST SHARING FOR LOW-INCOME SUBSIDY (LIS) AND DUAL ELIGIBLE
BENEFICIARIES UNDER THE MEDICARE PART D PROGRAM**

January 12, 2012

The National Alliance on Mental Illness (NAMI) is the nation's largest organization representing individuals living with serious mental illnesses and their families. As an organization representing and advocating on behalf of Medicare beneficiaries, NAMI has placed a high priority on making sure that Part D has worked to effectively provide drug benefits for beneficiaries living with serious conditions such as schizophrenia, bipolar disorder and major depression. Beneficiaries living with serious mental illness are more likely to qualify for LIS or be deemed dual eligibles. Even before passage of Medicare Part D in 2003, NAMI was working to make sure that the unique and complicated needs of these beneficiaries are taken into account – in terms of cost sharing protections, availability of plan options below the regional benchmark, formulary protections and imposition of utilization management such as step therapy, prior authorization and quantity limits.

Higher Rates of Brand Prescribing for LIS and Dual Eligibles are Based on a Complex Array of Factors

At the outset, NAMI recognizes that there are differences in the rates at which brand name and generic medications are prescribed and filled by LIS and dual eligible beneficiaries relative to the rest of the Part D population. In NAMI's view, this is a natural consequence of the mandatory cost sharing structure that Congress put in the statute in 2003. The legislative history of Part D makes clear that this structure was designed to protect the most vulnerable low-income beneficiaries in the program. By design, the differential in cost sharing between brand and generic medications for duals and LIS is significantly narrower than it is for beneficiaries above 135% of poverty. In NAMI's view, this cost sharing structure was put in place by Congress as a critical beneficiary access protection. Any proposal to change this structure must therefore be

viewed in terms of its potential impact on the ability of Medicare beneficiaries to use Part D access medications.

Unfortunately, the presentations on this issue that have been made by the Medpac staff at the November and December meetings failed to explore factors beyond cost sharing that might be driving higher rates of brand prescribing for LIS and duals. For example, the dual eligible population experiences significantly higher complex medical comorbidities that are likely to drive prescribing patterns. Many have complex drug regimens that can result in prescribing of brand products for which generic equivalents are not available. This is certainly the case in therapeutic categories where there are few generic medications available and where there can be significant variation within a therapeutic class with respect to both efficacy and side effect profiles.

The case of atypical antipsychotic medications provides an illustrative example. We have numerous clinical studies demonstrating that these medications (olanzapine, clozapine, quetiapine, risperdone, paliperidone, aripiprrole, to name a few) are not clinically interchangeable. These studies include the CATIE study, a randomized controlled trial funded by the National Institutes of Health which found that nearly 70% of subjects had to switch medications at least once during the study period, and nearly half switched medications at least twice. These medications vary significantly in terms of mechanism of action and side effect profiles. Since the inception of Part D, the majority of drugs in this class have not had generic equivalents available and as a result one would expect the brand prescribing rate to be higher in this class. What is important to note is that a higher rate of brand prescribing within this particular therapeutic class for duals and LIS beneficiaries is likely to be driven by factors beyond cost sharing – higher prevalence of serious mental illness in the dual and LIS population, efficacy and side effects associated with the drugs in the class for which the generics are available, etc.

Before moving forward with this proposal on increasing cost sharing for dual eligibles and LIS beneficiaries, NAMI would recommend that Medpac take into the complex factors beyond cost sharing that are driving prescribing patterns for this population of vulnerable low-income beneficiaries. What is clear to NAMI is that it is NOT the case that the current patterns of prescribing brand medications to dual eligible and LIS beneficiaries is driven by these beneficiaries demanding brand medications over generics. NAMI is concerned that the Medpac staff reports on this issue failed to present any evidence that higher rates of brand prescribing are driven by beneficiary demands placed on prescribers. In NAMI's experience, LIS and dual eligible beneficiaries are often passive participants in their treatment and rarely if ever make

demands on their doctors for prescribing a specific brand name product. In reality the prescribing a specific medication is completely out of control. It is therefore troubling to NAMI that these beneficiaries would be at risk of higher cost sharing as a result of treatment decision that is largely beyond their control.

NAMI would also like to raise the following additional concerns regarding both the Medpac proposal as well as the staff presentation and commissioner discussion at the December 15 meeting.

1) Generic Substitution v. Therapeutic Substitution

At the December 15 meeting, there was significant confusion as to the extent to which a proposed new cost sharing structure for dual eligible and LIS would apply. Would it apply across any therapeutic class for which generic alternatives are available within the class? Or would the higher cost sharing apply only for brand products for which a generic alternative is available for that particular medication? I want to be clear that NAMI has significant concerns with both interpretations.

Regardless, the confusion turns on the difference between therapeutic substitution and generic substitution. In case of the former, it is substitution of a different compound in order to access a generic product. In the case of the latter, it is substitution of a generic equivalent for the brand version of the same medication. During the discussion at the December 15 meeting, it was unclear if higher brand cost sharing would apply across both domains. Slide 4 of the staff presentation uses the term “lower-cost medications when available in a given therapeutic class.” Likewise, slide 5 contains the language “No change in cost-sharing amounts for drugs in a class with no generic substitutes” -- in other words, in order to escape higher cost sharing, the entire therapeutic class would have to be free of any generic substitutes.

As a result, NAMI cannot avoid the conclusion that the Medpac proposal would impose higher cost sharing on a beneficiary prescribed a medication for which there is no generic alternative, but for which a generic product available in the particular therapeutic class – but for which a serious side effect or diminished efficacy is associated with the alternative medication. In other words, to minimize cost sharing a dual eligible would be required to switch medications and risk significant medical complications. This is simply unacceptable to NAMI under any and all circumstances.

2) Creation of additional brand drug tiers for dual eligible and LIS beneficiaries

One notable difference in the proposals presented by the Medpac staff at the November and December meetings is the addition of separate cost sharing tiers for preferred and non-preferred brand drugs. The December staff recommendations included these separate tiers with options for \$6 cost sharing for preferred brand, and cost sharing as high as \$10 for non-preferred brand. Such a proposal would result in increases in cost sharing for dual eligible and LIS of more than 270%. This is alarming to NAMI given that all of these beneficiaries are under 135% of the federal poverty level that also had to meet an asset means test to qualify for LIS.

Nearly all dual eligible live on fixed incomes that for many are as low as \$600 per month, leaving them with little or no disposable income after basic living expenses such as rent, utilities and food. For many of these beneficiaries, even the current cost sharing structure of Part D imposes a significant burden – particularly for those with complicated drug regimens used to treat multiple chronic conditions (6 to 8 medications refilled twice each month can result in monthly cost sharing in excess of \$75 to \$80). Adding to this burden – even in cases where a generic alternative of a particular drug is not available is, in NAMI’s view, unfair.

3) Availability of \$0 cost sharing for generic medications for LIS and dual eligible

NAMI supports efforts to lower cost sharing for generic medications in Part D to \$0. As a number of Commissioners pointed out at the December 15 meeting, there are Part D plans that currently waive cost sharing for generics. Unfortunately, contrary to assertions made by several Commissioners, these plans are NOT allowed to waive cost sharing for LIS and dual eligibles enrolled in their plans. In fact, the Part D cost sharing structure for dual eligible and LIS is mandatory in the statute. Part D plans and retail pharmacists are required to assess these amounts. In fact, efforts were made as far back as 2005 to create a 3rd party structure to cover cost sharing for LIS and duals or allow pharmacies to waive them. However, concerns over antitrust and anti-kickback issues resulted in the FTC and the Justice Department blocking these efforts.

4) Seeking Part D savings through measures focused solely on dual eligible and LIS beneficiaries

NAMI is especially troubled that this proposal sets a new and dangerous precedent in Medicare policy – namely, seeking cost savings through imposition of a new policy focused solely on beneficiaries at or below 135% of poverty. These cost sharing protections, along with other features of Part D such as \$0 monthly premiums for drug plans priced at or below regional benchmarks, were put in the statute for a particular reason – to protect low-income beneficiaries AND to ensure that dual eligible whose prescription coverage was shifting from Medicaid to Part D were not worse off. Changing the Part D cost structure as Medpac is recommending breaks that promise.

Likewise, as a matter of equity and fairness it imposes the burden for generating savings to the program exclusively on the most vulnerable beneficiaries.

5) Existing Part D exceptions and appeals processes are insufficient to protect beneficiary access under a revised cost sharing structure

During the discussion of this proposal at the December 15 meeting, several commissioners and the Medpac staff noted that Part D plans are required to make exceptions and appeals processes available to beneficiaries to protect access in particular circumstances. These exceptions and appeals can be used to waive a prior authorization or step therapy requirement that is applied to a particular drug, allow for lower tier cost sharing or override a quantity limit imposed on a drug. For many beneficiaries these exception and appeals processes have been effective in protecting beneficiary access. It is important to note that to date LIS and dual eligible beneficiaries have NOT been able to use these exceptions and appeals process to get cost sharing waived as this is mandated in the statute.

In NAMI's experience in working directly with beneficiaries living with mental illness, these processes have been successful where a prescribing physician is willing and able to assist with documentation and clinical justification. Unfortunately, not all physicians have the time or patience to assist patients with exceptions and appeals. NAMI is therefore concerned with any proposed change for dual eligibles and LIS that relies on the current exceptions and appeals processes to override higher cost sharing in unique and special circumstances (inability of a patient to tolerate a generic, inappropriate therapeutic substitution).

Conclusion

NAMI would like to restate its opposition to proposals from Medpac to increase cost sharing in Part D for LIS and dual eligible beneficiaries under Part D. In NAMI's view, this proposal amounts to a dangerous and unprecedented shift in policy – seeking savings to the Medicare by enacting policies where the impact is focused solely on beneficiaries at or below 135% of the federal poverty level. It is simply unfair to impose increases in cost sharing of more than 250% for beneficiaries to continue accessing the medications that have been prescribed for them for management of a chronic illness. Further, any policy that requires a vulnerable extremely low-income Medicare beneficiary to switch to a separate medication in order to avoid higher cost sharing is likely to have grave negative consequences in terms of ongoing treatment adherence, and ultimately, long-term costs to Medicare associated with negative clinical outcomes among the sickest and most vulnerable beneficiaries. NAMI urges Medpac to reject this proposal.