NATIONAL ASSOCIATION OF Manufacturers

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March 7, 2014

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-4159-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: RIN 0938-AR37: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

The National Association of Manufacturers (NAM), is pleased to respond to the proposed rule published in the Federal Register on January 6, 2014 with comments on the "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," (proposed rule). The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs nearly 12 million men and women, contributes more than $1.8 trillion to the U.S. economy annually, has the largest economic impact of any major sector and accounts for two-thirds of private-sector research and development. The NAM is the powerful voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States. We are disappointed that Centers for Medicare & Medicaid Services (CMS) is making changes to the program that would negatively affect jobs and the U.S. economy and request that the proposed rule be withdrawn in its' entirety. In lieu of complete withdrawal, we offer the following concerns.

Any Willing Pharmacy

Preferred network plans allow for more streamlined management across network pharmacies, improving efficiencies and lowering costs. For example, the average monthly premium for Medicare Part D plans with preferred networks is 17 percent less than in plans without preferred networks. CMS' plan will eliminate these efficiencies by including an "Any Willing Pharmacy" requirement. This will result in significant changes or elimination of up to 50 percent of Part D plan choices during 2015 and 2016. The "Any Willing Pharmacy" requirement is also expected to cause material premium and cost sharing increases for about 6.9 million Medicare Part D beneficiaries who are currently enrolled in preferred pharmacy networks and up to $9.3 billion in federal government cost increases over the next 10 years.[1] Medicare should be looking to support successful programs that control costs, not creating ways to financially burden the program.

[1] Kaczmarek, Stephen J., Sheldon, Andrea, Liner David M., *"Survey Analysis of January 2014 CMS Medicare Part D Proposed Rule,"* Milliman Report, February 2014

In addition, and perhaps more alarming, is that the "Any Willing Pharmacy" concept is based on a dangerous interpretation on the non-interference clause set forth in the original legislation authorizing the Part D program. The legislation was specifically written to prevent government interference in price negotiations. The proposed rule, however, seeks to find a way around that prohibition by putting legislative language and intent aside and interfering in price negotiations. This is a dangerous idea that has potential to completely unravel a successful, budget-conscious program.

Plan Limitations

The proposed rule further limits free market competition by imposing limits on the number of plans a sponsor may offer in a region. By only allowing one basic and one enhanced plan, competition is stifled and costs will increase. A recent CBO analysis stated clearly that more plans participating in any one region lowered bids. Again, this limitation significantly undermines the structure of the Part D program and takes away choices currently available to seniors and future retirees. Further, this new restriction appears to be in direct contradiction to the intent of Congress when it passed legislation authorizing the creation of Medicare Part D in 2003. Throughout the drafting and negotiating process, proposals much like the limitation proposed here, were specifically rejected out of concern for the impact it would have on competition.

Limiting Protected Classes

Due to a new structure for defining drugs that are mandated to be covered by Part D, mental health drugs and post-transplant medications would no longer be considered protected classes of medicines. This, again, is an unnecessary modification of policy that has been in place since the outset of the program and has contributed to the success of it over the past ten years. Although this is meant as a cost containment measure to drive use of generic equivalents, it seems to ignore current data – 83 percent of all antidepressants used in Part D in 2011 were generics and when a generic substitute is available in this class, it was used about 99 percent of the time. Seemingly similar patients often respond differently to the same drug: while one patient will respond well, a similar patient will have no or a suboptimal response. Drugs in the same class often have different side-effect profiles as well, and patients are often best suited to one particular drug. As a consequence, there will be upward pressure on costs elsewhere in the healthcare system if patients do not have access to necessary medications and require more expensive in-patient care.

Medication Therapy Management

CMS proposes to expand eligibility for Medication Therapy Management (MTM) which will make more than half of Medicare beneficiaries will be eligible. Although CMS seeks to lower costs through increased optimization of care, the NAM is concerned that the less stringent requirements in the proposed rule merely expands the MTM benefit without taking into consideration the clinical value. If this program is to be expanded it should look to specifically

identify populations that would be best suited for the services before requiring additional benefits. Simply expanding the scope of MTM programs would increase costs for manufacturers to provide Part D coverage to their retirees without any proven clinical benefit.

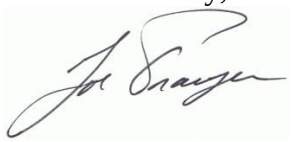
Mail Order Delivery

Although manufacturers are advocates for efficient logistics systems, we are concerned that CMS is mandating mail-order delivery times that may not be reflective of real-world circumstances. Mail order pharmacies provide clear financial benefits to beneficiaries, plan sponsors and the Medicare program itself through lower copayments and drug costs. For example, a recent CMS analysis found that mail order pharmacies' overall costs were 16 percent less than retail pharmacies. We are concerned that setting mandatory delivery times would result in decreased use of mail order pharmacies, despite their proven value for seniors, plan sponsors and the Medicare program. Therefore, we suggest that CMS remain flexible with regard to these provisions and allow for exceptions to be made for circumstances that may be beyond control of the pharmacy or the plan.

Conclusion

The NAM appreciates the opportunity to submit these comments on behalf of our 12,000 members, many of which sponsor Part C and D plans for their retirees. We believe the proposed regulations make significant changes to the programs that are beyond or contrary to legislative intent when the programs were created. Seniors would lose access to the plans they like, while taxpayers would be responsible for increased program costs resulting from these changes. Our concern is that ultimately these proposed changes will undermine what have been successful programs for American seniors and other taxpayers.

Sincerely,



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