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Dr. Donald Berwick
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Application of Federal Anti-Kickback Statute to Manufacturer-Sponsored Pharmaceutical Assistance Plans

Dear Administrator Berwick:

I am concerned that the strict, through well-reasoned, application of the Federal Anti-Kickback Statute to the Medicare Part D program may restrict the opportunity of middle income senior citizens access to manufacturer-sponsored pharmaceutical assistance programs that would otherwise defray their cost of medical care. While the purchasing power of many seniors income continues to stagnate or decline, the cost of living and medical care is rising, necessitating the need for such assistance programs. There are justifiably sound reasons to protect seniors from unscrupulous business practices, but such policies should be sensitive to particularized situations where the gain provided to seniors in the form of decreased out-of-pocket costs greatly outweighs the risk of abuse.

It is my understanding that under current federal regulations, pharmaceutical companies are not able to subsidize the cost of prescription drugs for seniors participating in Medicare Part D unless they do so through a state-sponsored or charitable pharmaceutical assistance program. These regulations were clearly promulgated so as to avoid unlawful inducement and steering of seniors onto particular drugs so as to artificially inflate the revenues of manufacturers.

As you know, many seniors are prescribed specific drugs by their doctors to combat health complications. These prescriptions often last indefinitely and there may be no feasible alternative to the drug prescribed (at least, until a generic is offered). These drugs are prescribed to ensure that seniors can lead long and healthy lives when they have demonstrated risks. While pharmaceutical companies may offer direct co-payment assistance for these drugs, Medicare beneficiaries are not eligible. In addition, many working class seniors are not eligible for state pharmaceutical assistance programs meant to defray the cost of copayments due to income restrictions. If no generic alternative exists, and seniors are prescribed on a drug indefinitely, limiting the risk of steering and inducement, I believe there is a strong argument for crafting an exemption to the prohibition against participation in manufacturer pharmaceutical assistance programs to defray the cost of prescription drugs.

Over the long-run, there will surely be other ways to defray the cost of prescription drugs for seniors. Providing a forum to allow Medicare to negotiate with pharmaceutical companies directly for the price of prescription drugs would be helpful in defraying senior's out-of-pocket costs. Further, as intellectual property ownership evolves, generics will enter the market, decreasing the cost of prescriptions. The rebates provided to seniors to close the Part D donut hole as part of the Affordable Care Act will also go a long way to providing assistance in paying for catastrophic care coverage. However, until such proposed and pending changes are passed and fully implemented, many working class seniors will remain ineligible for co-pay programs they should be eligible for.

Thank you for your attention to this matter.

Sincerely,



BRIAN HIGGINS
Member of Congress