Insight

Legal Analysis of Proposed Part D Rule Finds HHS Acting Unlawfully

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Following the proposed Part D rule released by the Centers for Medicare and Medicaid Services (CMS) on January 10, 2014, the American Action Forum commissioned a legal opinion from the firm Boyden Gray and Associates, PLLC on the rule's new interpretation of the non-interference provision. The opinion finds that the rule is

> *"breaking sharply from the long-settled understanding of the provision's categorical prohibition against HHS interfering in Part D drug price negotiations."*

When the Part D program was established by the Medicare Modernization Act (MMA) in 2003, it was agreed that the law prohibited the Department of Health and Human Services (HHS) from involving itself in drug price contracts; this was included in the law as a non-interference provision. It states clearly that the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and [Prescription Drug Plan] sponsors."

However, the latest CMS regulatory overreach interprets this to mean that the administrative agencies cannot intercede between drug manufacturers and pharmacies or between manufacturers and sponsors, but the negotiation between pharmacies and sponsors is fair game.

According to Boyden Gray and Associates' legal analysis, the new interpretation strays drastically from the original legislative intent, the previous HHS interpretation of the provision, and the clearly written legislation. It is thus unlawful.

The noninterference provision was controversial and much debated when MMA passed and there is no shortage of documents pointing to the original Congressional intent.

> *"Simply put, at no stage in the pre-enactment legislative debate did Congress evince any understanding that the noninterference clause did not protect negotiations between "pharmacies and PDP sponsors."*

Similarly, the opinion notes multiple HHS documents referring to the non-interference provision as interpreted to protect all drug price negotiations, as well as proposals to repeal the non-interference provision by legislators who wanted HHS to have more authority over Part D negotiations. And lastly, Congress could have clearly demarcated which contracts were off-limits with the use of punctuation. Instead all three entities are listed, with no commas or interjections, which points to the law's clear meaning that HHS may not interfere in any of the aforementioned negotiations.

As a result the opinion finds the new proposed regulation to be an unlawful regulatory overreach.

Read the full legal opinion below.