

Allen Amendment #1

Prescription Drug Comparative Effectiveness/ Cost-Effectiveness

Summary

The amendment requires the CMS Administrator to provide for the conduct of research on the comparative effectiveness and cost-effectiveness of prescription drugs that account for high levels of expenditures or use by individuals in the Medicare program. In addition, the amendment directs CMS to submit an annual report to Congress delineating their findings, making the report publicly available on the internet. The amendment allows the CMS Administrator to enter into agreements with the Directors of the National Institutes of Health (NIH) and the Agency for Health Care Research and Quality (AHRQ) to conduct the research and disseminate the findings.

The amendment is based on H.R. 2356, The Prescription Drug Comparative Effectiveness Act of 2003, introduced by Rep. Allen June 11.

Talking points:

- Currently, drug companies promote their drugs as safer or more effective than competing drugs, but this promotion is too often based on poorly-designed studies or other questionable sources of information.
- The FDA is responsible for determining safety and effectiveness of prescription drugs (does the drug treat the condition its label says it treats), but there is no government entity responsible for examining the comparative effectiveness of prescription drugs (e.g., is drug A more effective at treating a particular condition than drug B). FDA judges the effectiveness of drugs compared to a placebo but does not ordinarily make judgments about the comparative effectiveness of drugs for the same indication, nor does it take into account relative costs.
- The goal of the amendment is to establish an independent source of evidence-based research on drug comparative effectiveness and cost-effectiveness. NIH and AHRQ would develop an extended source of comparative information on drugs, accessible to clinicians, private physicians, and the public.
- Our current system of drug company marketing to doctors, persuading them to use the newest, and generally more expensive treatments, coupled with direct-to-consumer advertising to patients can lead to over-prescribing and increased reliance on the newest, and often most expensive, prescription drugs to treat a particular condition.
- The amendment recognizes that doctors need a range of treatment options in order to make informed choices based on individual patient needs. The amendment would ensure that physicians have access to objective, evidence-based, non-biased information on which drugs are likely to be most effective at treating a particular condition.