VIA Electronic Submission to http://www.regulations.gov

August 13, 2010

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
United States Department of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210
Attention: RIN 1210-AB42

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIIO-9991-IFC
P.O. Box 8016
Baltimore, MD 21244

CC:PA:LPD:PR [REG-118412-10]
Room 5205
Internal Revenue Service
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

Re: RIN 1210-AB42, OCIIO-9991-IFC, and REG-118412-10; Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act.

Dear Sir or Madam:

Thank you for the opportunity to submit our comments on the IRS, EBSA and HHS interim final rules with comment period (IFC) regarding the requirements for health care plans to follow in order to claim grandfathered health plan (GHP) status and clarifying the provisions of the Patient Protection and Affordable Care Act (PPACA) that apply to GHPs and how they apply. As the three agencies consider issues pertinent to determining GHP status and what statutory and regulatory provisions apply to GHPs, the National Community Pharmacists Association (NCPA) appreciates the opportunity to share our perspectives.

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NCPA represents America's community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises, and chains. Together these represent an $84 billion healthcare marketplace, employ nearly 60,000 licensed pharmacists, employ over 300,000 fulltime employees, and dispense nearly half of the nation's retail prescription medicines. NCPA members are the primary providers of pharmaceutical drugs and supplies to millions of Americans and are concerned about the impact of the GHP rule as it applies to prescription drug plans.

NCPA requests that the three agencies make two changes to the IFC. First, NCPA requests that the agencies promulgate rules mandating that health plans lose their GHP status if they change a GHP to either mandate or incentivize beneficiaries to use mail order pharmacies instead of community-based retail pharmacies. Second, NCPA requests that the agencies allow PDPs to maintain GHP status when they make changes to their drug formularies, which promote the use of generic drugs. NCPA believes that the suggested changes further promote the goals of the PPACA of preserving the ability to maintain existing coverage, while expanding access to and improving the quality of coverage.

GHP Status Should Cease When a Health Plan Makes a Change to Incentivize or Mandate Beneficiary Use of Mail Order Pharmacies

The PPACA seeks to balance the goal of beneficiaries maintaining existing coverage, if they choose to, with the goal of expanding beneficiary access to coverage and improving the quality of coverage. The IFC aims to accomplish this goal by allowing health plans to make some adjustments while maintaining GHP status without allowing those same plans to make unreasonable changes. The latter would undermine the whole legislative purpose of a GHP and the concept of maintaining existing coverage. More specifically, the IFC discusses the agencies' intent to allow reasonable routine changes by health plans without those plans risking the loss of GHP status.

If the agencies were to allow a health plan to maintain GHP status while making changes to incentivize or mandate beneficiary use of mail order pharmacies, they would then be allowing fundamental core changes to the nature of the plan. Beneficiaries would lose access to community pharmacists, who provide valuable face-to-face advice and counseling to beneficiaries on medication management and related issues. Studies have demonstrated that community pharmacists' face-to-face patient interactions have a positive impact on patient behavior that is not seen in other contexts, such as when patients receive their medications through mail order.[1] In other words, any change that encourages or mandates patients to refrain from engaging in such interactions restricts patient access to a valuable service and changes the structure of the health plan.

[1] Journal of the American Pharmacists Association. "Patients' needs and interest in a self-pay medication therapy management service." Jan/Feb 2010, pgs 72-77. 2 Journal of the American Pharmacists Association. "Impact of drug cost and use of Medicare Part D of medication therapy management services, delivered in 2007." Nov/Dec 2009, pgs 813-820.

Some groups may submit comments claiming that mail order saves beneficiaries money, but the cost-saving claims of mail order are illusory. Mandatory mail order drug plans create 3.3 times more waste than prescription drug plans that allow patients the freedom to obtain their prescription drugs and pharmacy services at a community pharmacy.[2] This high rate of waste implies that patients using mail order pharmacies are receiving in bulk more than what they intend to consume, creating the increased potential risk of overuse and abuse in the future due to the stockpiling of outdated prescription drugs.

Given the lack of true cost savings from mandatory or incentivized mail order, along with the concomitant restriction on patient access to valuable face-to-face pharmacy counseling and advice, the agencies should not allow health plans to maintain GHP status when they make plan changes to incentivize or mandate beneficiary use of mail order pharmacies.

Changes to Drug Formularies That Encourage the Use of Generics Should Not Trigger a Loss of GHP Status

The IFC implies that reasonable, routine plan changes should not trigger the loss of GHP status. One such routine change is for a health plan to charge a higher co-pay for a brand drug when a generic drug becomes available. When a generic drug becomes available the re-assignment of the brand drug to a higher cost-sharing tier is routine, often occurring automatically. Accordingly, such changes within formulary tiers of a health plan are not benefit changes and, therefore, NCPA requests that the agencies not view such formulary changes as triggering a loss of GHP status. The use of a generic instead of a brand is not a change in coverage, because the drug is still available to the patient.

We also are concerned with the potential that plans will change their formulary designs by creating or expanding a list of "specialty medications" in order to shift patients to their own mail order pharmacy, or only allow medications to be distributed through certain pharmacies. We believe that this reduces beneficiary access and is a change in coverage that should result in loss of GHP status.

Conclusion

The IFC regarding the requirements to maintain GHP status should recognize the accessibility to high quality services that community pharmacies provide to beneficiaries. The IFC changes requested by NCPA serve the legislative and regulatory goals of allowing flexibility to decrease beneficiary drug costs and increase beneficiary drug access, while remaining true to the concept that beneficiaries should be allowed to keep their existing coverage if they so choose. In conclusion, NCPA respectfully requests that: 1) GHP status cease when health plans make changes to existing plans to mandate or incentivize beneficiaries to use mail order pharmacies and 2) Health plans be allowed to change drug formulary tier composition in order to promote beneficiary access to generic medications without risking loss of their GHP status, but not create specialty tiers for the sole purpose of shifting patents to their own mail order pharmacies.

[2] Daniel Halberg, Erin Smith, and Kevin Sedlacek. "Effect of Mail-Order Pharmacy Incentives on Prescription Plan Costs", University of Arkansas for Medical Sciences College of Pharmacy, October 2000.

NCPA appreciates the opportunity to comment on RIN 1210-AB42, OCIIO-9991-IFC, and REG-118412-10. Please do not hesitate to contact Christopher R. Smith at chris.smith@ncpanet.org, (703) 683-8200 if you have any questions.

Sincerely,

Ronna B. Hauser, PharmD
Vice President, Policy and Regulatory Affairs
National Community Pharmacists Association (NCPA)