DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Beneficiary Choices
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR BENEFICIARY CHOICES

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To: Part D Sponsors

From: Abby L. Block, Director

Subject: Formulary Changes During the Plan Year

Both industry best practices and the best interests of Medicare beneficiaries call for limited formulary changes during the benefit year. Formulary stability is extremely important so that enrollees maintain access to the benefit they chose during enrollment as represented to them by the plan.

However, prescription drug use and pricing is constantly evolving, and new drug availability, new medical knowledge, new drug pricing arrangements, and new opportunities for improving safety and quality in prescription drug use at a low cost will inevitably occur over the course of the year. These new developments may require formulary changes during the year in order to provide high-quality, low-cost prescription drug coverage.

Under Part D, no beneficiaries will be subject to a discontinuation or reduction in coverage of the drugs they are currently using, except for clear scientific and cost reasons including the availability of a new generic version of the drug or new FDA or clinical information.

All proposed formulary changes, excluding formulary expansion changes, must be submitted to CMS for review and approval. We will continue to review these requests, as we have been doing, using the principles outlined below, which include a comprehensive review of a formulary each time a change request is submitted. CMS will continue to ensure that each formulary provides a broad range of medically appropriate drugs and does not discriminate or substantially discourage enrollment of certain groups of beneficiaries.

Formulary Changes During the Plan Year

Q: What changes can Part D plans make to their formularies during the plan year?

A: Both industry best practices and the best interests of Medicare beneficiaries call for limited formulary changes during the plan year. We believe that formulary stability is extremely important so that enrollees maintain access to the benefit they chose during enrollment as represented to them by the plan. However, prescription drug therapies are constantly evolving, and new drug availability, new medical knowledge, and new opportunities for improving safety and quality in prescription drug use at a low cost will inevitably occur over the course of the

year. As recognized in the statute and regulations, these new developments may require formulary changes during the year in order to provide high-quality, low-cost prescription drug coverage.

We have a 4 part policy regarding formulary changes:

1. Part D plans may expand formularies by adding drugs to their formularies, reducing co-payments or coinsurance by lowering the tier of a drug, or deleting utilization management requirements any time during the year.

2. Part D plans may not change their therapeutic categories and classes in a formulary other than at the beginning of each plan year, except to account for new therapeutic uses and newly approved Part D drugs.

3. Formulary Maintenance Changes: After March 1, Part D plans may make maintenance changes to their formulary, such as replacing brand-name with new generic drugs or modifying formularies as a result of new information on drug safety or effectiveness. Those changes must be made in accordance with the approval procedures described below and following 60 days notice to CMS, SPAPs, prescribers, network pharmacies, pharmacists and "affected enrollees".

4. Other Formulary Changes: Part D plans may only remove Part D drugs from their formulary, move covered Part D drugs to a less preferred tier status, or add utilization management requirements in accordance with the approval procedures described below and following 60 days notice to CMS, SPAPs, prescribers, network pharmacies, pharmacists, and "affected enrollees". For these additional types of formulary changes approved by CMS for 2006, Part D plans should make such formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the plan year. CMS expects that Part D plans will continue to comply with this policy in 2007 and subsequent plan years, and will include such assurances in their future bids and contracts.

Note: Part D plans are not required to obtain CMS approval or give 60 days notice when removing formulary drugs that have been withdrawn from the market by either the FDA or a product manufacturer.

Additional detail on these policies is included below.

Formulary Maintenance Changes
In order to promote best practices and protect the interests of Medicare beneficiaries, CMS will generally give positive consideration to the following types of formulary changes:

1. Removal or placement in less preferred tier of a brand drug upon the availability and addition of an A-rated generic or multi-source brand equivalent, at a lower tier or cost to the beneficiary.
2. Removal of a non-Part D drug inadvertently included on the formulary.
3. Removal of a drug based upon a new FDA "black box" warning or market withdrawal.
4. Removal or placement in a less preferred tier based upon new clinical guidelines or information recognized by CMS (e.g. CDC's recommendation against using older anti-virals for treatment and prophylaxis of the flu)

5. The addition of utilization management when necessary to effectuate other approved formulary changes (e.g. prior authorization on a brand drug when generic is now available on formulary at a lower cost), to help determine B vs. D coverage (subject to CMS guidance on least burdensome ways to make this determination), or to promote safe utilization of a Part D drug based upon new clinical guidelines or information.

Part D plans will need to provide this type of justification when submitting these formulary change requests, but may assume that change requests based upon these justifications are approved if they do not hear from CMS within 30 days of submission. Part D plans are required to send 60 days notice to CMS, SPAPs, prescribers, network pharmacies, pharmacists, and "affected enrollees" (except for FDA or manufacturer withdrawals).

Other Formulary Changes
Experience with formulary management indicates that the vast majority of formulary changes are "maintenance" changes that would generally be approved by CMS. CMS will review additional types of formulary change requests and their corresponding justification. For these additional types of formulary changes approved by CMS for 2006, Part D plans should make such formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the plan year. CMS expects that Part D plans will continue to comply with this policy in 2007 and subsequent plan years, and will include such assurances in their future bids and contracts. These additional types of change requests include, but are not limited to:

- Changing preferred or non-preferred formulary drugs, adding utilization management, or increasing cost sharing on preferred drugs (unrelated to the reasons stated above);
- Removing dosage forms; or
- Exchanging therapeutic alternatives (either by formulary addition/removal or tier exchanges).

If CMS disapproves a formulary change request, the justification for disapproval will generally be based on one of the following:

- The reasonableness and/or necessity for the proposed change in the context of preventing any appearance of "bait and switch" in the formulary. Medicare beneficiaries select Part D plans, in part, based on the formulary that is marketed during annual open enrollment and, therefore, have a legitimate expectation that they will have continuing access to coverage of the Part D drugs they are using throughout the plan year. This beneficiary expectation will be balanced against the plan's desire to practice good formulary management in order to provide a low-cost, high-quality prescription drug benefit that continues to effectively meet the needs of beneficiaries. Part D plans may avoid any appearance of a "bait and switch" concern by exempting enrollees who are currently using the affected drugs from the formulary change for the remainder of the plan year.
- The proposed change on its face in the context of substantially discouraging enrollment by certain beneficiary groups.
- The impact of the proposed change on the formulary as a whole to ensure the formulary continues to satisfy the minimum formulary requirements established by CMS.

Because these additional types of change requests will require more extensive review by CMS, Part D plans must not implement such changes until they receive explicit notification of approval

from CMS and must not issue any beneficiary notices of such forthcoming changes prior to receiving explicit and affirmative CMS approval.