30.3 - Formulary Changes
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

The removal of any drug, whether a Part D drug or a supplemental drug offered as a supplemental benefit under an enhanced alternative benefit design, is subject to the formulary change guidance contained in the following sections.

30.3.1 - Limitation on Changes in Therapeutic Classification
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Except as CMS may permit to account for new therapeutic uses and newly approved Part D drugs, a Part D sponsor may not change formulary categories and classes after the last CMS specified HPMS formulary upload date for the upcoming contract year.

30.3.2 - Limitation of Formulary Changes Prior to Beginning of Contract Year
(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Except when the *FDA* deems a Part D drug unsafe or a manufacturer removes a Part D drug from the market, a Part D sponsor may not remove a covered Part D drug from its formulary, or make any change in preferred or tiered cost-sharing status of a covered Part D drug, between the beginning of the annual coordinated election period described in section 42 CFR *§*423.38(b) and 60 days after the beginning of the contract year associated with the annual coordinated election period.

30.3.3 - Midyear Formulary Changes
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Both industry best practices and the best interests of Medicare beneficiaries call for limited formulary changes during the contract year. CMS believes that formulary stability is extremely important so that enrollees maintain access to the benefit they chose during enrollment as represented to them by the sponsor. However, prescription drug therapies are constantly evolving, and new drug availability, medical knowledge, and 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.

30.3.3.1 - Policy Regarding Formulary Changes
(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

The following is CMS' policy regarding formulary changes:

- Part D sponsors may expand formularies by adding drugs to their formularies, reducing copayments or coinsurance by placing a drug on a lower cost-sharing tier, or deleting

utilization management requirements at any time during the year. *Such changes can be implemented immediately by a sponsor and should be submitted to CMS at the next scheduled opportunity.*

- *CMS considers negative formulary changes to include the following: 1) removal of a drug from a formulary; 2) increasing the cost-sharing status of a drug on the formulary subsequent to a change in tier; 3) adding, or making more restrictive: a) prior authorization requirements, b) quantity limits, c) step therapy requirements, and 4) imposing other restrictions on a drug that require CMS approval.*

CMS also considers the expiration of an approved exception to be a negative formulary change for purposes of required advance notice to the beneficiary. Sponsors should consult chapter 18, section 30.2 for further guidance on beneficiary notification requirements for approved exceptions, available at https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip*.*

- Formulary Maintenance Changes: After March 1, Part D sponsors 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.

- Non-maintenance (Other) Formulary Changes: Part D sponsors may remove Part D drugs from their formulary, move covered Part D drugs to a less preferred tier status, or add utilization management requirements. For these additional types of formulary changes approved by CMS, Part D sponsors should make such formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the contract year.

Part D sponsors must receive CMS *approval of* any changes to *their* formulary; however, Part D sponsors are not required to obtain CMS approval for drugs that have been withdrawn from the market by either the FDA or a product manufacturer.

Beginning in CY 2014, while CMS will continue to offer a summer formulary update, formulary changes during this particular update submission will be limited to: 1) the addition of drugs that are new to the summer release of the Formulary Reference File (historically posted in July); and 2) the submission of negative changes on brand name drugs, only if the equivalent generic is added to the summer FRF and corresponding formulary file. As noted previously, positive formulary changes can be implemented at any time, consistent with guidance on the timely ongoing review of all new FDA-approved drug products and indications.

Sponsors should consult the Prescription Drug Benefit Manual, Chapter 2 (Medicare Marketing Guidelines), Section 60.5, "Formulary and Formulary Change Notice Requirements", and Chapter 5 for further guidance related to print and website versions of their formularies.

30.3.3.2 - Formulary Maintenance Changes

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

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:

- Removal or placement in a less preferred tier of a brand name drug upon the availability and addition of an A-rated generic or multi-source brand name equivalent, at a tier *with lower* cost to the beneficiary.

- Removal of a non-Part D drug inadvertently included on the formulary.

- Addition of utilization management tools based upon a new FDA *boxed* warning.

- Removal of a drug based upon a new FDA market withdrawal notice.

- Removal of a drug based on long term shortage and market availability (described in chapter 5, section 50.13).

- 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 antivirals for treatment and prophylaxis of the flu).

- The addition of utilization management when necessary to effectuate other approved formulary changes (e.g., prior authorization on a brand name 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 sponsors will need to provide a justification when submitting formulary maintenance change requests, but they may assume that change requests based upon these justifications are approved if they do not hear from CMS within 30 days of submission.

30.3.3.3 - Non-maintenance (Other) Formulary Changes

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

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 non-maintenance formulary change requests and their corresponding justification. Part D sponsors should make such formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the contract year. 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 sponsors, 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 contract year. This beneficiary expectation will be balanced against the sponsor'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 sponsors 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 contract 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 sponsors 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.

30.3.4 - Provision of Notice Regarding Formulary Changes

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors must provide notice of formulary changes as outlined in the following sections. Additionally, for formulary maintenance changes (described in section 30.3.2), CMS will not require Part D sponsors to wait for approval before sending notice of a proposed formulary change to required parties. For these changes, a Part D sponsor may choose to provide notice to CMS and other required parties at the same time. Part D sponsors will provide notice to CMS via the HPMS system, which will also require plans to specify the intended effective date. Although sponsors may provide notice to all required parties prior to receiving CMS approval, sponsors might prefer to wait so that they do not risk sending notice of a change that is subsequently disapproved by CMS. For formulary non-maintenance or "other" changes (described in section 30.3.3.3), Part D sponsors must not issue any beneficiary notices until CMS has explicitly approved the non-maintenance change.

30.3.4.1 - Beneficiary Notice Requirements

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Prior to making any *negative formulary* change *during the contract year*, a Part D sponsor must either:

- Provide direct written notice to affected enrollees at least 60 days prior to the date the change becomes effective; or

- At the time an affected enrollee requests a refill of the Part D drug, provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed and written notice of the formulary change.

If a beneficiary is not "affected" by a formulary change (in other words, exempted from a formulary change), notice is not required.

The written notice must contain the following information:

- The name of the affected covered Part D drug;

- Whether the Part D sponsor is removing the covered Part D drug or changing its preferred or tiered cost-sharing status;

- The reason why the Part D sponsor is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

- Alternative drugs in the same therapeutic category or class or cost-sharing tier and expected cost-sharing for those drugs; and

- The means by which enrollees may obtain a coverage determination under 42 CFR §423.566 or exception under 42 CFR §423.578.

As an alternative to providing written notice, Part D sponsors may provide such notice electronically if, and only if, an enrollee affirmatively elects to receive such notice electronically.

30.3.4.2 - Notice for Other Entities

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Prior to making any *negative formulary* change *during the contract year*, a Part D sponsor must provide at least 60 days' notice to CMS, State Pharmaceutical Assistance Programs (as defined in 42 CFR §423.454), entities providing other prescription drug coverage (as described in 42 CFR §423.464(f)(1), authorized prescribers, network pharmacies, and pharmacists prior to the date such change becomes effective.

To the extent possible, sponsors may elect to provide State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage (as described in 42 CFR §423.464(f)(1), authorized prescribers, network pharmacies, and pharmacists an annual notice providing information on the sponsor's formulary change policy (i.e., length of notice, methods of

communication with beneficiaries, and any electronic notices providers may receive at the point-of-sale regarding formulary status) and the sponsor's Web site where these entities can verify the formulary status of particular drugs.

30.3.4.3 - Provision of Notice Regarding Formulary Changes *Subsequent to Removal from the Market*

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D sponsors may immediately remove from their formularies covered Part D drugs deemed unsafe by the *FDA* or removed from the market by their manufacturer without meeting the advance notice requirements specified in this section. However, Part D sponsors must provide retrospective notice of any such formulary changes to affected enrollees, CMS, State Pharmaceutical Assistance Programs (as defined in 42 CFR *§*423.454), entities providing other prescription drug coverage (as described in 42 CFR *§*423.464(f)(1), authorized prescribers, network pharmacies, and pharmacists consistent with the requirements set forth in this section. CMS expects that this retrospective notice will occur as soon as possible to inform enrolled beneficiaries of potential safety concerns surrounding medications they are taking, especially those beneficiaries who may have a 90 day supply and will not interact with the pharmacy for an extended period.

In instances where there has been an announcement of a market withdrawal, but the withdrawal has not yet taken place, Part D sponsors may opt to either remove the drug immediately with a retrospective notice to "affected enrollees" or provide an advance notice. CMS expects Part D sponsors to consider all pertinent information available from the FDA related to the withdrawal.

30.3.4.4 - Notice Requirements for Pending Formulary Changes

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

When a Part D sponsor notifies CMS of a formulary change in HPMS, the change is assigned a prospective effective date. During the period of time between when a Part D sponsor has notified CMS of a prospective change and the actual effective date of that change, Part D sponsors must ensure appropriate beneficiary protections are implemented should a beneficiary who has not been notified of the change present with a new prescription for the drug whose formulary status is changing.

For maintenance changes outlined in section 30.3.3.2, the Part D sponsor must implement the beneficiary notice requirements contained in section 30.3.4.1 (i.e., 60 days of advance written notice before implementing the change for the individual). For example, assume on March 1st, a Part D sponsor notifies CMS via HPMS that it is removing a brand name drug from its formulary due to the availability of a new generic. The sponsor indicates the effective date for this formulary change will be May 1st. If a beneficiary were to present on April 1st with a new prescription for the brand name drug pending removal, the Part D sponsor would provide written notice of the change and not implement the change until June 1st, in order to provide the full 60 days of advance notice to that beneficiary.

A Part D sponsor may elect to provide written notice to all of its enrollees of a pending formulary maintenance change in lieu of notifying only the "affected enrollees." Such an approach would satisfy the beneficiary notice requirements in section 30.3.4.1 because all enrollees, including "affected enrollees" would receive advance notice of a formulary change. In addition, it would preclude the plan from needing to extend the formulary change effective date for those enrollees who present with a new prescription for the drug between the date when a Part D sponsor notifies CMS of a prospective change and the actual effective date of that change. However, Part D sponsors are still required to provide advance written notice of a formulary change and a 60 day-supply of the drug whose formulary status is changing to those beneficiaries who enroll in the plan after the initial advance formulary change notice, as described above.

For non-maintenance changes outlined in section 30.3.3.3, the Part D sponsors must not implement the formulary change for a beneficiary who presents with a new prescription for a pending formulary drug. In accordance with our non-maintenance formulary change policy, enrollees currently taking the affected drug must be exempt from the formulary change for the remainder of the contract year. For example, assume on March 1st, a Part D sponsor notifies CMS via HPMS it is removing a drug from its formulary with no replacement. CMS approves the change. The sponsor indicates the effective date for this formulary change will be May 1st. If a beneficiary were to present on April 1st with a new prescription for the drug pending removal, the Part D sponsor would not implement this change for the beneficiary for the remainder of the contract year.

30.3.5 - Formulary Change Notice in Advance of Upcoming Contract Year

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Enrollees must receive an annual notice of change (ANOC) by *September 30th* prior to the upcoming contract year. The ANOC is intended to outline benefit changes for the upcoming year including changes in cost-sharing and drug tier structures. Because the upcoming year's formulary is viewed as a new formulary, Part D sponsors are not required to identify specific drug changes impacting enrollees in their explanation of benefits, or provide a 60-day notice of changes for the upcoming year's formulary. However, enrollees must receive a comprehensive or abridged formulary with the ANOC, which will provide enrollees with at least *90* days to review the new formulary to determine if their medications are covered and whether the cost-sharing for their covered medications will change in the upcoming contract year.