30 - Formulary Requirements

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

A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet requirements for the following:

- Pharmacy and Therapeutics committee;
- Provision of an adequate formulary;
- Transition process;
- Limitation on changes in therapeutic classification;
- Provision of notice regarding formulary changes;
- Limitation of formulary changes prior to beginning of contract year;
- Provider and patient education; and
- Formulary changes during the contract year.

30.1 - Pharmacy and Therapeutics (P&T) Committee

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

A Part D sponsor's formulary must be developed and reviewed by a P&T committee that meets specific requirements with respect to:

- Membership;
- Conflict of interest;
- P&T member disclosure to CMS;
- Meeting administration;
- Formulary management;
- Formulary exceptions; and
- P&T committee role.

30.1.1 - Membership

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

Part D sponsors' P&T committee membership must satisfy the following requirements:

- P&T committee members must come from various clinical specialties that adequately represent the needs of sponsors' enrollees.

- A majority of the P&T committee members must be practicing physicians, practicing pharmacists, or both. *CMS defines a practicing physician or pharmacist to be an individual who has an active professional license to practice in the United States or one of its Territories and is currently practicing in the U.S. or one of its Territories.*

- At least one P&T committee practicing pharmacist and one practicing physician must be an expert in the care of elderly or disabled persons.

- At least one P&T committee practicing pharmacist and one practicing physician must be independent and free of conflict with respect to the Part D sponsor and pharmaceutical

manufacturers. Such P&T committee members may have certain non-employee relationships with pharmaceutical manufacturers (for example consulting, advisory, or research relationships) and still be considered independent and free of conflict provided those relationships do not constitute significant sources of income and they do not otherwise have a conflict of interest that would compromise their independence. In addition, panel providers in a staff model HMO may be considered independent and free of conflict to the extent that any remuneration received from a Part D sponsor is limited to his or her clinical responsibilities for the care of plan enrollees.

30.1.2 - Conflict of Interest

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

P&T committee members should sign a conflict of interest statement revealing economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions.

30.1.3 - P&T Committee Member Disclosure to CMS

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

In the event the Part D sponsor has entered into a confidential agreement such that the Pharmacy Benefits Manager (PBM) will not disclose its P&T committee membership to the Part D sponsor, then it is the Part D sponsor's responsibility to notify CMS that this information will be submitted by the sponsor's PBM. Moreover, the Part D sponsor must ensure that the PBM notifies CMS of the P&T committee membership. The Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract and the sponsor must ensure that the PBM notifies the sponsor that this information has been successfully submitted to CMS.

30.1.4 - Meeting Administration

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

The Part D sponsor's P&T committee should meet on a regular basis, but no less than quarterly. P&T committee decisions regarding formulary development or revision must be documented in writing.

30.1.5 - Formulary Management

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

Part D sponsor's P&T committee will consider the following:

- The P&T committee must review for clinical appropriateness the practices and policies for formulary management activities, such as prior authorizations, step therapies, quantity limitations, generic substitutions, and other drug utilization activities that affect access. P&T committee recommendations regarding these activities are advisory only and not binding on the Part D sponsor.

- Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe, and cost effective drug therapy.

- The P&T committees will be required to establish and document procedures to ensure appropriate drug review and inclusion. This includes documentation of decisions regarding formulary development and revision and utilization management activities (42 CFR §423.120(b)(1)(viii)). P&T committee recommendations regarding which Part D drugs are placed on a sponsor's formulary are binding on the Part D sponsor.

- Clinical decisions by the P&T committee should be based on scientific evidence and standards of practice, including peer reviewed medical literature, well-established clinical practice guidelines, and pharmacoeconomic studies, as well as other sources of appropriate information.

- Drugs' therapeutic advantages in terms of safety and efficacy must be considered when selecting formulary drugs and placing them on formulary tiers.

- The P&T committee will make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days *of its release onto the market* and will make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met.

- The P&T committee will evaluate and analyze treatment protocols and procedures related to the sponsor's formulary at least annually.

- The P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.

- Part D sponsors that change *pharmacy benefit managers (*PBMs*)* mid-year are required to continue the existing formulary. Decisions regarding formulary inclusion made by the previous PBM's P&T committee are binding on the assuming PBM. CMS will not approve negative formulary change requests for the purpose of aligning an existing formulary with that of a new PBM.

30.1.6 - Formulary Exceptions

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

P&T committees must review for clinical appropriateness protocols and procedures for the timely use of and access to both formulary and non-formulary drug products. Part D coverage determinations and appeals information can be found in chapter 18 of this manual.

30.1.7 - P&T Committee Role in Transition

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

At a minimum, a sponsor's transition process, the minimum requirements of which are detailed in section 30.4, will address procedures for medical review of non formulary drug requests and, when appropriate, a process for switching new Part D sponsor enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. CMS will look to transition process submissions for assurances that a sponsor's P&T committee will review and provide recommendations regarding the procedures for medical review of non-formulary drug requests. P&T committee involvement will help ensure that transition decisions appropriately address situations involving enrollees stabilized on drugs that are not on the sponsor's formulary (or that are on the formulary but require prior authorization or step therapy under a sponsor's utilization management requirements) and which are known to have risks associated with any changes in the prescribed regimen.