PDBM Chapter 6:
The Part D Formularies Awaken

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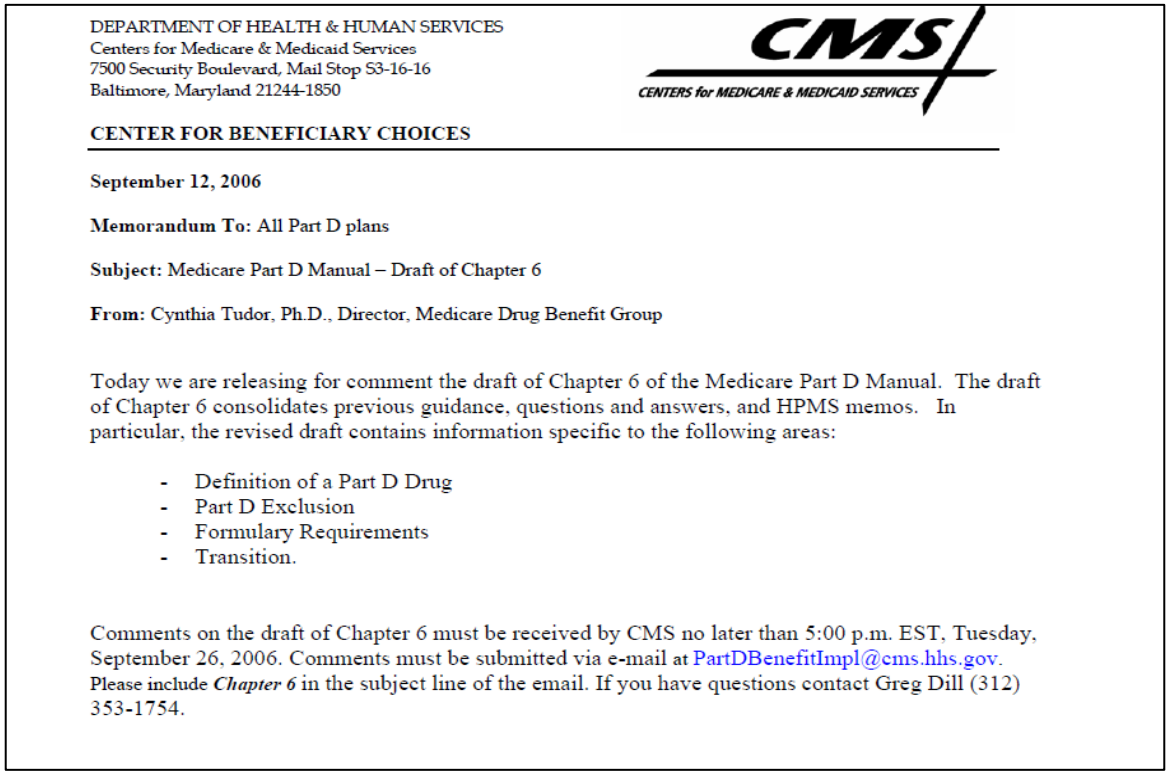
May 5, 2016

Agenda

- Chapter 6 history and timeline
- Summary of the 2016 revision to Chapter 6 of the Prescription Drug Benefit Manual
- Key changes made to Chapter 6 guidance and discuss questions that have come up since its publication
- Updates to the formulary reference file and HPMS formulary process
- Formulary update policies review
- Resources & Q/A

Chapter 6 History & Timeline



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

CMS
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September 12, 2006

Memorandum To: All Part D plans

Subject: Medicare Part D Manual – Draft of Chapter 6

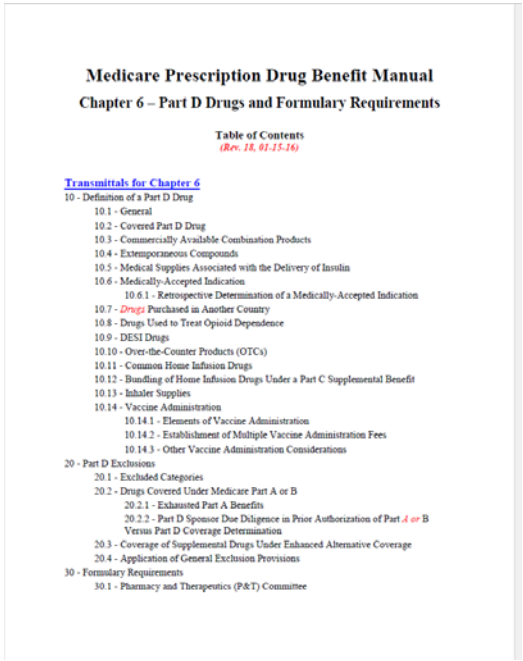
From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

Today we are releasing for comment the draft of Chapter 6 of the Medicare Part D Manual. The draft of Chapter 6 consolidates previous guidance, questions and answers, and HPMS memos. In particular, the revised draft contains information specific to the following areas:

- Definition of a Part D Drug
- Part D Exclusion
- Formulary Requirements
- Transition.

Comments on the draft of Chapter 6 must be received by CMS no later than 5:00 p.m. EST, Tuesday, September 26, 2006. Comments must be submitted via e-mail at PartDBenefitImpl@cms.hhs.gov. Please include ***Chapter 6*** in the subject line of the email. If you have questions contact Greg Dill (312) 353-1754.

Chapter 6 History & Timeline



Medicare Prescription Drug Benefit Manual

Chapter 6 – Part D Drugs and Formulary Requirements

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(Rev. 18, 01-15-16)

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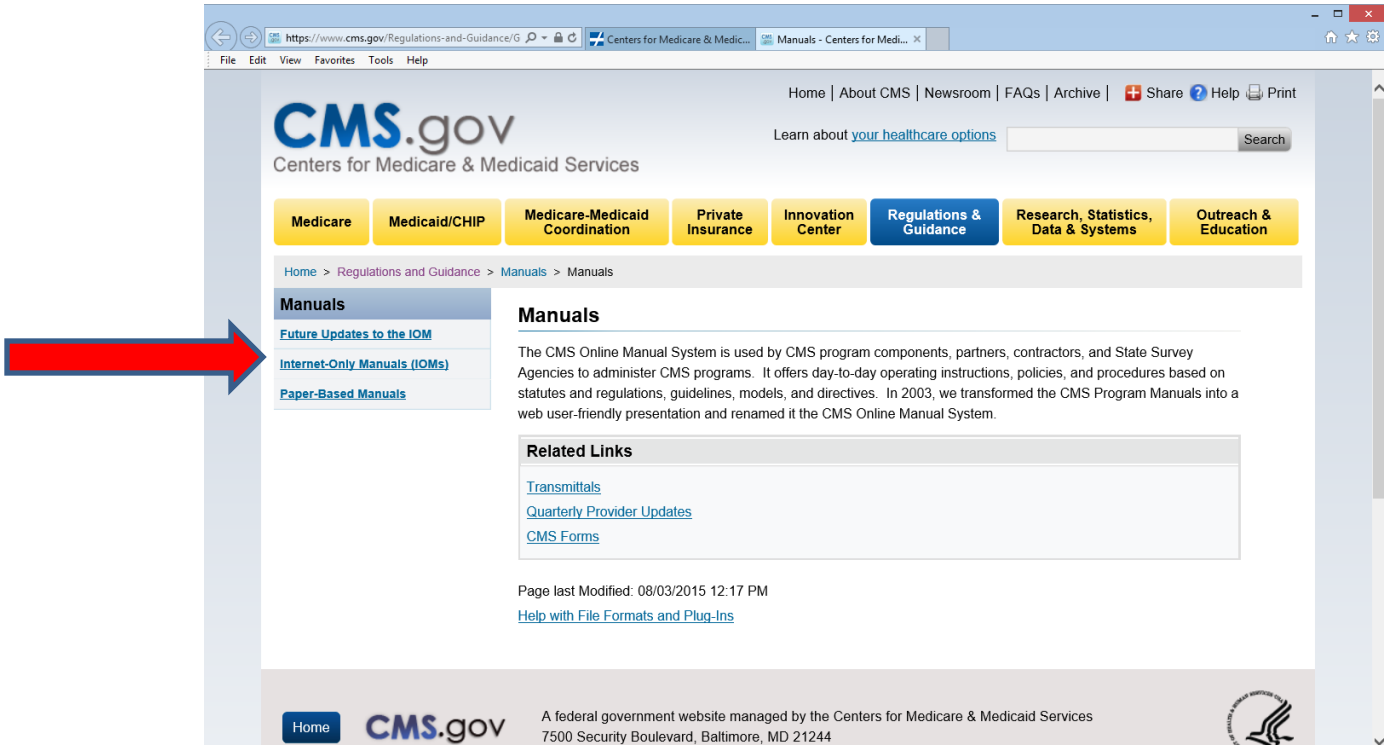
Chapter 6 History & Timeline



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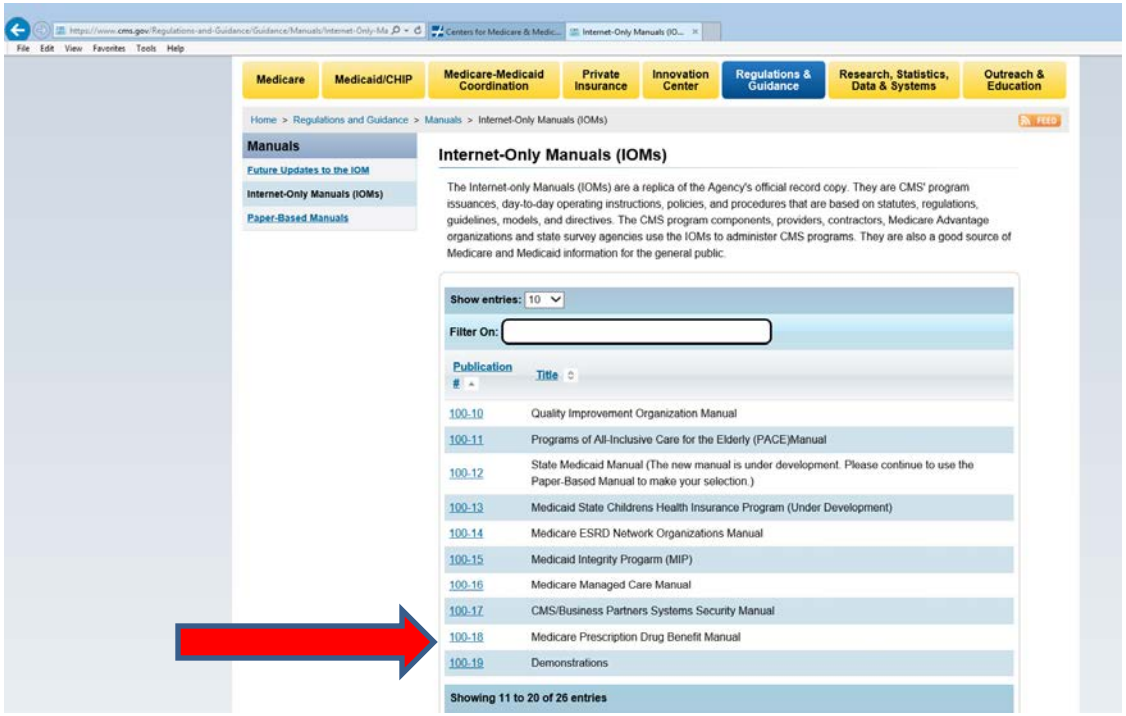

Chapter 6 History & Timeline

Medicare Prescription Drug Benefit Manual

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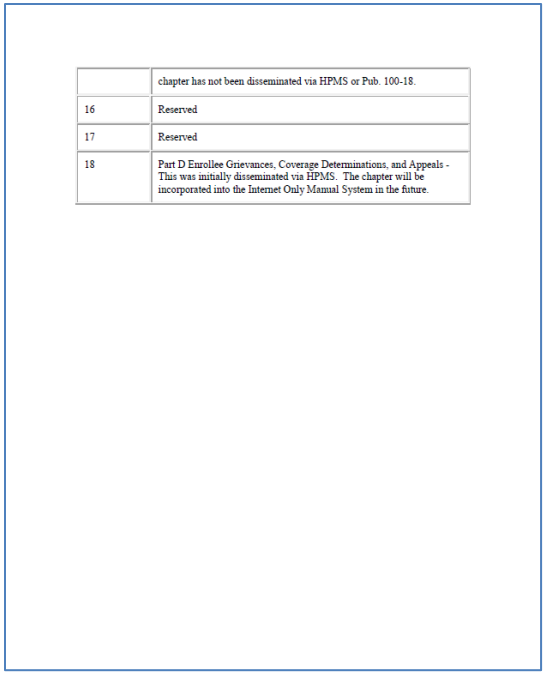

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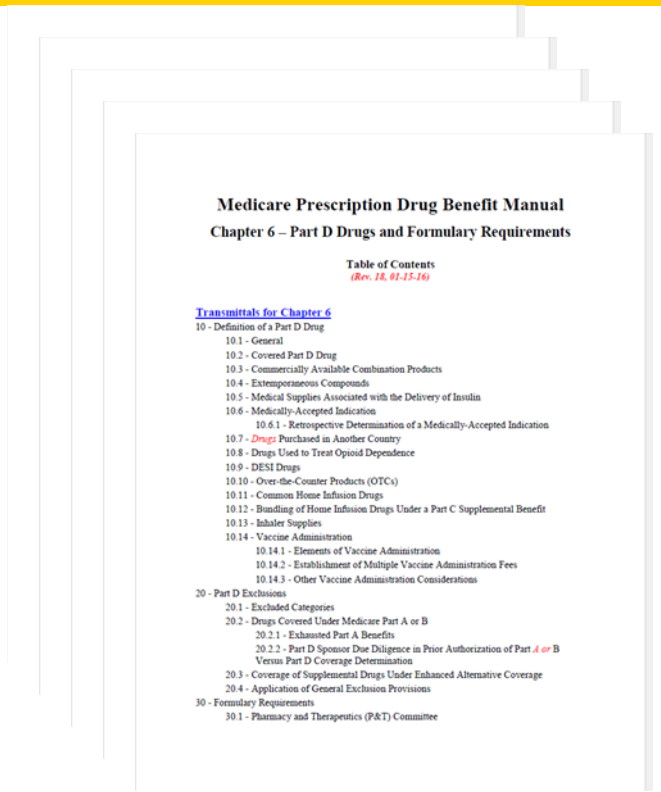

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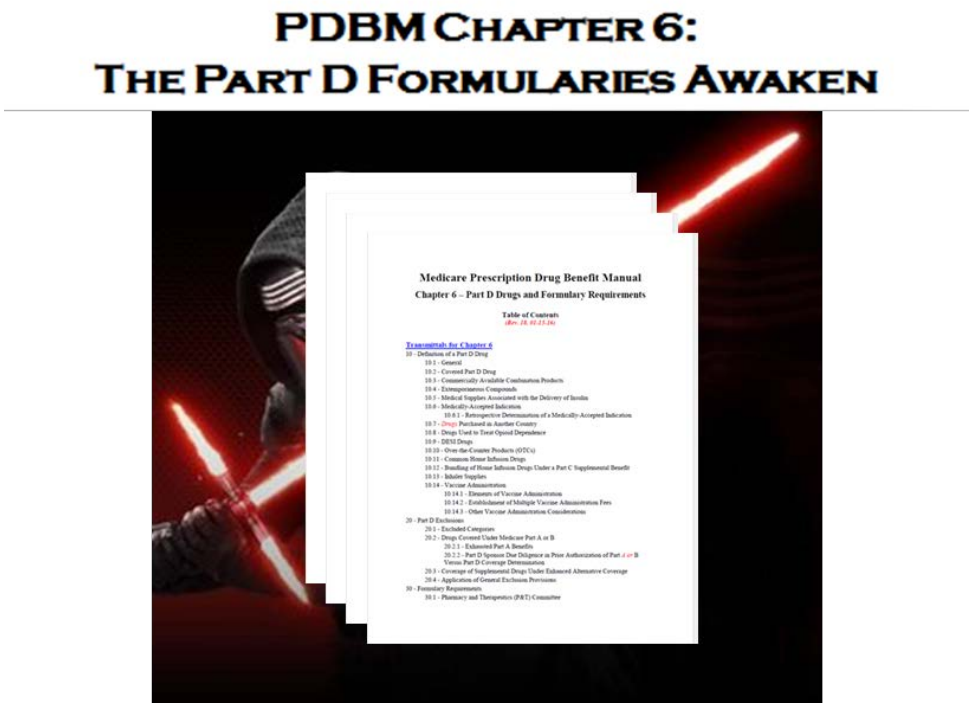


http://scifi.stackexchange.com/questions/111585/what-are-all-the-known-lightsaber-designs

Chapter 6 Summary

- The updated chapter reflects updates from pertinent final regulations, Call Letters, and memoranda.
- Changes were also made in consideration of feedback relating to operationalizing the Part D benefit.
- As part of this revision, we attempted to decrease redundancies where possible. For instance, this updated version uses more cross-references to related policies or regulations to avoid summaries of the same information in multiple locations throughout the manual.

Key Chapter 6 Changes

Key Chapter 6 Changes

10.3 – Commercially Available Combination Products

Only those combination products approved and regulated in their combination by the FDA as a drug, vaccine, insulin, or biological product, as described in paragraph (i), (ii), (iii), or (v) of the Part D drug definition at §423.100 are eligible for Part D coverage. This requirement for FDA approval applies to commercially available combination products meant for broad distribution…

Key Chapter 6 Changes

10.3 – Commercially Available Combination Products

Scenario 1: Super Strong Bones + B: is this a Part D drug?

a. **Yes, if medically appropriate for Mrs. Jones**
b. **No, stand alone vitamin B is OTC, not Part D**
c. **It depends on how it is packaged/approved**

Key Chapter 6 Changes

10.4 – Extemporaneous Compounds

- Only compounds that contain at least one ingredient that independently meets the definition of a Part D drug, and that do not contain any ingredients covered under Part B as prescribed and dispensed or administered, may be covered under Part D.
- For a Part D compound to be considered on-formulary all ingredients that independently meet the definition of a Part D drug must be considered on-formulary.
- Bulk powders do not satisfy the definition of a Part D drug and are not covered by Part D.
- For low-income subsidy beneficiaries, the copayment amount is based on whether the most expensive ingredient that independently meets the definition of a Part D drug in the Part D compound is a generic or brand name drug.

Key Chapter 6 Changes

10.4 – Extemporaneous Compounds

Question 2: True or False

Part D sponsors must consider extemporaneous compounds including at least one Part D eligible ingredient as on-formulary.

Key Chapter 6 Changes

10.6 – Medically-Accepted Indication

- Part D sponsors must reference all CMS-recognized compendia to determine whether there are any supportive citations prior to determining that a drug is not being used for a medically-accepted indication.
- All Part D sponsors should consistently utilize prior authorization (PA) for those drugs with the highest likelihood of non-Part D covered uses, as detailed in section 30.2.2.3 unless plans are able to reliably use tools other than PA to determine appropriate coverage for the drug.

Key Chapter 6 Changes

10.6 – Medically-Accepted Indication

Scenario 3: Compendia support – is this MAI?

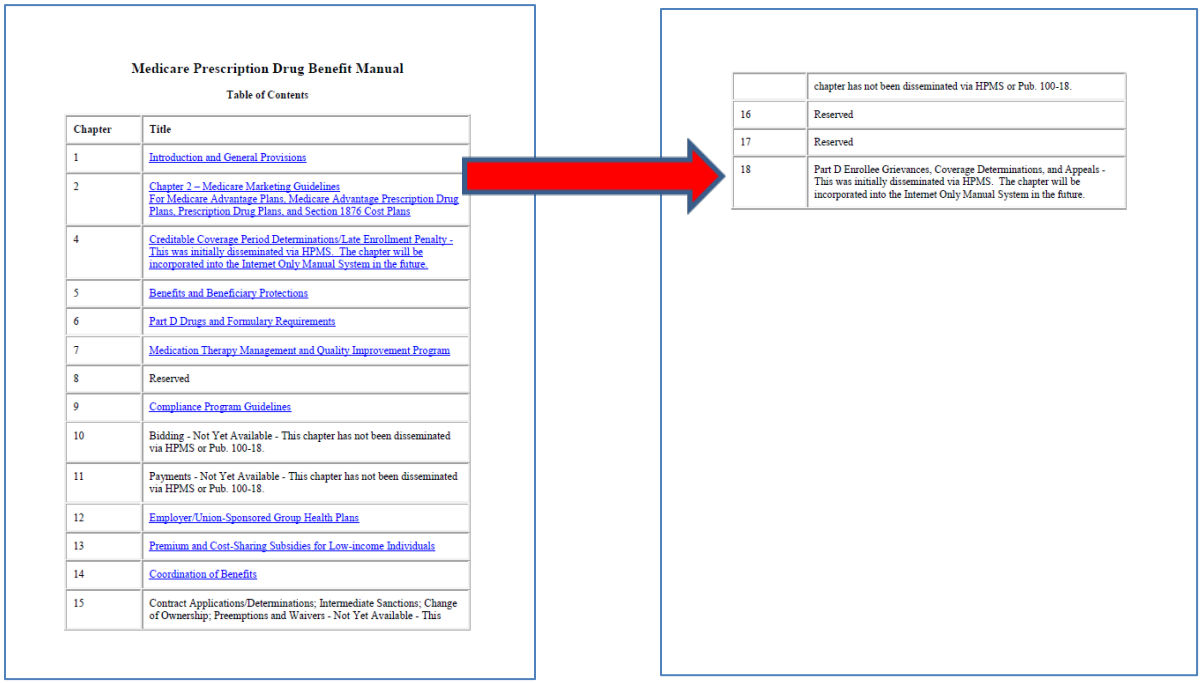
- **Indication is on-label**
- **Indication is supported in AHFS-DI**
- **Indication is supported in DRUGDEX®**

Key Chapter 6 Changes

10.6.1 – Retrospective Determination of a Medically-Accepted Indication

- When retrospective review of point of sale claims adjudication determines that a drug was dispensed for a non-medically-accepted indication, the PDE should be deleted and accumulators adjusted.
- Sponsors should additionally reference all applicable PDE guidance and, when applicable, guidance in the Prescription Drug Benefit Manual, Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals, regarding required notices for coverage determinations.

Key Chapter 6 Changes



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Key Chapter 6 Changes

10.6.1 – Retrospective Determination of a Medically-Accepted Indication

Example: An individual receives a prescription and takes *the* drug within a common dosing regimen (i.e., one tablet daily). Several months later, that individual's physician writes a new prescription for an increased dosage of that drug. The second prescription triggers a quantity limit *claim edit* (for example, based on safety limits). *A*s a result, the individual's physician *requests a coverage determination from the plan and* submits evidence to support an exception to the quantity limit. Based on that evidence, the Part D sponsor makes a determination that the drug was not prescribed for a medically-accepted indication.

Key Chapter 6 Changes

20.1 – Excluded Categories

- Bottom line: Part D does not cover drugs or classes of drugs, or their medical uses, which are excluded from coverage or otherwise restricted under section 1927(d)(2) of the Act.
- Cough and cold medications are eligible to meet the definition of a Part D drug in clinically relevant situations other than those of symptomatic relief of cough and/or colds. For example, when “cough” medications are used to treat a medical condition that causes a cough, such as the use of bronchodilators for the treatment of bronchospasm in asthma, CMS does not consider these “cough” medications as excluded drugs; and therefore, these medications may be covered under Part D. However, antitussives used to treat cough symptoms, and not the underlying medical condition causing the cough, are excluded from basic Part D coverage regardless of the medical condition causing the cough.

Key Chapter 6 Changes

20.1 – Excluded Categories

Question: True or False

A standard Part D plan may cover a nasal decongestant for a member with a history of diabetes, high blood pressure, and gout whose breathing is labored due to lasting congestion from a head cold 2 weeks ago.

Key Chapter 6 Changes

20.2 – Drugs Covered Under Medicare Part A or B

- Hospice
- ESRD

Key Chapter 6 Changes

30.2.2 – Formulary Benefit Management Tools

- A POS edit that is triggered based on approved formulary criteria or other allowable CMS restriction does not constitute a coverage determination unless the plan treats the presentation of a prescription as a request for a coverage determination.
- However, a plan that approves or denies a drug through application of such criteria has made a coverage determination that is subject to all applicable coverage determination standards, timelines, and requirements outlined in Chapter 18.

Key Chapter 6 Changes

30.2.2.1 – Utilization Management Edits Requiring CMS Submission and Approval

- 3 types of POS edits
- Prior Authorization, Step Therapy, Quantity Limits
- Opioid specific safety edits

30.2.2.2 – Utilization Management Edits Not Requiring CMS Submission and Approval

- Safety edits, utilization review edits
- Cumulative APAP edits

Key Chapter 6 Changes

30.2.2.3 – Application of Prior Authorization

Part D sponsors should consistently utilize PA for those drugs with the highest likelihood of non-Part D covered uses, based on the following definitions:

- High likelihood that coverage is available under Parts A or B (versus D) for the drug as prescribed and dispensed or administered
- High likelihood that the drug is excluded from Part D coverage
- High likelihood of use for non-medically-accepted indications

Key Chapter 6 Changes

30.3.3.1 – Policy Regarding Formulary Changes

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.

Key Chapter 6 Changes

30.3.3.1 – Policy Regarding Formulary Changes

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.

Key Chapter 6 Changes

30.4 – Transition

For the purposes of transition requirements in section 30.4, CMS defines non-formulary Part D drugs to mean: (1) Part D drugs that are not on a sponsor's formulary; (2) drugs previously approved for coverage under an exception once the exception expires, and (3) Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy, or that have an approved QL lower than the beneficiary's current dose, under a plan's utilization management requirements.

Key Chapter 6 Changes

30.4.10.1 – Prescriber Notification of Transition Fills

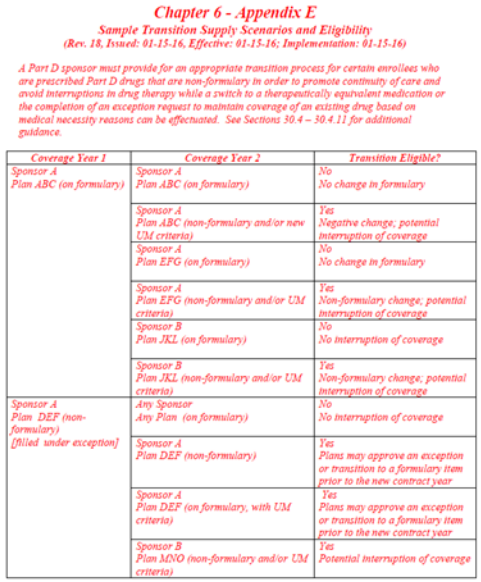
CMS believes that prescriber notification is a means of further strengthening beneficiary protections when dealing with formulary changes or utilization management protocols for necessary medications, because the prescriber is in the best position to advise the beneficiary of the benefits or risks of switching to a different medication.

Key Chapter 6 Changes

- **Appendices:**
  - **A** – *removed*
  - **B** – Part D Drugs/Supplemental Drugs Summary Table
  - **C** – Medicare Part B versus Part D Coverage Issues
  - **D** – The most commonly prescribed drug classes for the Medicare population
  - **E** – Sample Transition Supply Scenarios and Eligibility

Key Chapter 6 Changes

- **Appendix E -** Sample Transition Supply Scenarios and Eligibility



Chapter 6 - Appendix E

Sample Transition Supply Scenarios and Eligibility

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

A Part D sponsor must provide for an appropriate transition process for certain enrollees who are prescribed Part D drugs that are non-formulary in order to promote continuity of care and avoid interruptions in drug therapy while a switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons can be effectuated. See Sections 30.4 – 30.4.11 for additional guidance.

Coverage Year 1	Coverage Year 2	Transition Eligible?
Sponsor A Plan ABC (on formulary)	Sponsor A Plan ABC (on formulary)	No No change in formulary
	Sponsor A Plan ABC (non-formulary and/or new UM criteria)	Yes Negative change; potential interruption of coverage
	Sponsor A Plan EFG (on formulary)	No No change in formulary
	Sponsor A Plan EFG (non-formulary and/or UM criteria)	Yes Non-formulary change; potential interruption of coverage
	Sponsor B Plan JKL (on formulary)	No No interruption of coverage
	Sponsor B Plan JKL (non-formulary and/or UM criteria)	Yes Non-formulary change; potential interruption of coverage
Sponsor A Plan DEF (non-formulary) [filled under exception]	Any Sponsor Any Plan (on formulary)	No No interruption of coverage
	Sponsor A Plan DEF (non-formulary)	Yes Plans may approve an exception or transition to a formulary item prior to the new contract year
	Sponsor A Plan DEF (on formulary, with UM criteria)	Yes Plans may approve an exception or transition to a formulary item prior to the new contract year
	Sponsor B Plan MNO (non-formulary and/or UM criteria)	Yes Potential interruption of coverage

Key Chapter 6 Changes

Appendix E - Sample Transition Supply Scenarios and Eligibility

Coverage Year 1	*Coverage Year 2*	*Transition Eligible?*
Sponsor A *Plan ABC (on formulary)*	*Sponsor A* *Plan ABC (on formulary)*	*No* *No change in formulary*
	Sponsor A *Plan ABC (non-formulary and/or new UM criteria)*	*Yes* *Negative change; potential interruption of coverage*

Frequently Asked Formulary Questions

- Quantity Limits (QLs)
- Formulary Updates
- Formulary Reference File (FRF)
- Utilization Management (UM) Criteria Updates

Question

- How has the submission and review of quantity limits (QLs) changed?

QL Reminders

- QLs that allow for the dispensing of a given drug up to the FDA-approved maximum daily dose are not required to be submitted to CMS for review
- Sponsors should submit QLs based on the daily dose allowed over a one-month period for nearly all drugs that are subject to a QL edit
- QLs are not to be used to otherwise restrict quantities below the approved benefit maximum entered in the plan benefit package (PBP)

QL Type

- Yoda: “Always two there are, no more, no less”
- QL Type 1
  - Based on daily dose
  - Majority of formulary QLs
- QL Type 2
  - Based on a quantity over time other than daily dose
  - Should be rarely used on formulary
  - Use of QL Type 2 will be subject to CMS review and approval

QL Units on FRF

- New for CY 2017
- Sponsors should use the FRF QL units as a basis for their submitted QL amounts and days
- The units on the FRF are useful for determining QLs for products with unique dosage forms or circumstances such as reconstituted vials, certain inhalers, or syringes
- The designations of each, milliliters, or grams are based on the application of the NCPDP billing unit standard logic
- For products that could fall into multiple QL units – such as milliliters or each, sponsors are encouraged to use the logic described in the NCPDP billing unit standard

Question

- Are Part D sponsors prohibited from making changes to their formularies between the summer update window and the beginning of the plan year?

<Yes/No Polling Question to Assess Degree of Misunderstanding>

Yoda Quotes Relevant to Formulary Updates

- “Difficult to see. Always in motion is the future.”
- “Always pass on what you have learned.”
- “Many truths that we cling to depend on our point of view.”

Formulary Updates Prior to the Start of the Plan Year

- The summer limited update window is the final opportunity for sponsors to make certain negative formulary changes prior to the start of the plan year (i.e., maintenance changes when new generics are added to the FRF).

Formulary Updates Prior to the Start of the Plan Year

- However, sponsors can make enhancements to their formularies – such as adding newly approved drugs – at any time, including before the start of the plan year
  - Marketing materials must be updated
  - Changes must be reflected in the first available HPMS submission
  - Changes will not be reflected in Medicare Plan Finder until after the change is made in HPMS

Questions

- When can plans submit negative formulary change requests (NCRs)?

- How long does it take for CMS to approve an NCR?

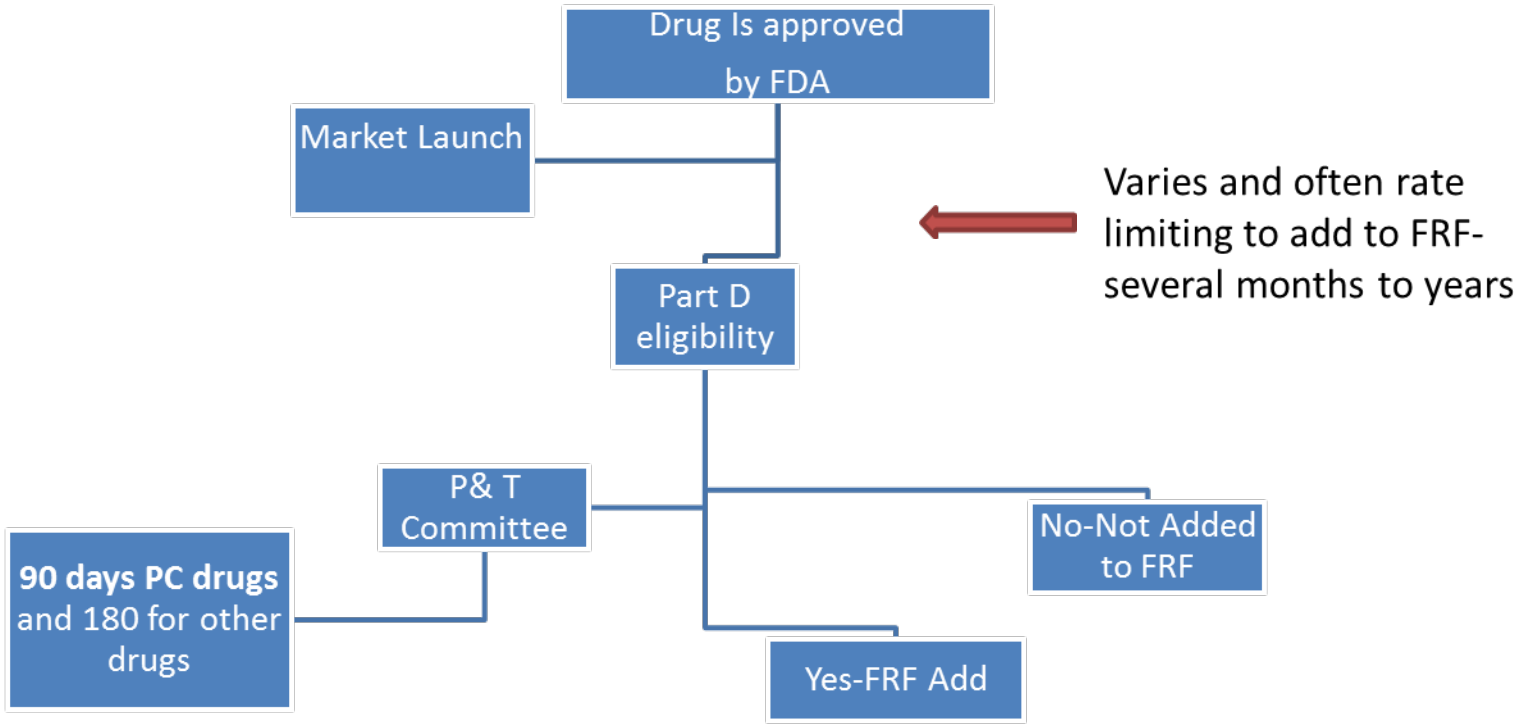
Formulary NCRs

- Plans can submit NCRs from December 31st thru July 31st
- Plans may opt to notify affected enrollees and other required parties at the same that they notify CMS to expedite the implementation of the change
  - Should ensure change is consistent with CMS requirements in order to avoid rescinding change notices
- Brand changes may be requested before the newly approved generic is added to the FRF. However, change cannot be implemented until the offsetting generic is added to formulary
- For CY 2016 CMS currently approves maintenance NCRs for an average of 12 days within submission

Question

- How long does it take for a drug to be added to the FRF?

Reference File Time Line



Question

- Can plans cover drugs that are not on the FRF?

  <Yes/No Polling Question to Assess Degree of Misunderstanding>

Questions

- Can UM be applied to drugs that are on a plan's formulary but not on the FRF?

  <Yes/No Polling Question to Assess Degree of Misunderstanding>

Drugs not on FRF

- Plans can add drugs to their formulary that are not on the FRF, such as new-to-market drugs. UM may be applied to these drugs.
  - The additions can adjudicate at POS immediately and must be reflected in updates to marketing materials
  - Formulary additions should be submitted via HPMS as soon as they appear on the FRF
  - An FRF add request must be submitted to CMS for covered drugs that are not yet on the FRF
  - If UM is required, the edits and criteria will be reviewed upon HPMS submission, and may require modification prior to CMS approval

Question

- Can UM and/or safety edits be applied to drugs that are non-formulary?

Non-formulary Drugs

- PA, ST, or QLs within FDA-labeled dosing guidelines must not be applied to drugs not on the formulary. Non-formulary drugs are subject to the general formulary exception requirements.
- However, safety edits, such as maximum dose limitations or cumulative MED edits, may be applied to non-formulary drugs.

Questions

- Is a beneficiary who receives a transition fill of a protected class drug that has PA or ST requirements exempt from those requirements for subsequent fills?

<Yes/No Polling Question to Assess Degree of Misunderstanding>

Transition Fills for Protected Class Drugs

- If a sponsor allows an initial fill of a protected class drug because it cannot determine at the point of sale that an enrollee is not currently taking the drug (during transition or otherwise), the sponsor shall treat such enrollees as currently taking the drug. Therefore, any protected class PA or ST requirements for new starts are no longer applicable after the first fill has been provided.

Questions

- Can plans routinely update UM criteria?

- Do UM criteria updates require CMS approval?

Updating Utilization Management Criteria

- Existing PA or ST criteria should only require updates in rare or extraordinary circumstances
- Sponsors should perform necessary QA checks in advance of HPMS submission in order to avoid having to update during the plan year
- Criteria may be written in a manner to allow the inclusion of additional drugs without the need for subsequent criteria updates

Updating Utilization Management Criteria

- Process outlined in the January 19, 2016, HPMS Formulary Information Memo
  - Completion of a UM Change Template stating the reason for updating current criteria
    - Removal of a restriction, Addition of drug(s) to existing criteria, Addition of a new indication, Restriction based on a new Black-Box Warning/FDA Safety Communication, or Other extraordinary circumstance
  - Altered templates or templates containing inaccurate information will be rejected
  - Do not submit templates for non-clinical changes such as spelling, grammar

Updating Utilization Management Criteria

- Hepatitis C Criteria Updates
  - Use of “Criteria will be applied consistent with current AASLD/IDSA guidance” rather than restating information that is already contained within the guideline update

Yoda

- “May the Force be with you”

RESOURCES

CMS strives for accuracy in all guidance and welcomes feedback on the changes in this version, as well as requests for additional changes going forward. Any suggestions or questions regarding this manual chapter should be directed to:

PartDPolicy@cms.hhs.gov

RESOURCES

For any formulary related questions, please contact the Division of Formulary and Benefits Operations at:

PartDformularies@cms.hhs.gov

Questions