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

CENTER FOR MEDICARE

TO: All Prescription Drug Plan and Medicare Advantage-Prescription Drug Plan Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C&D Data Group

RE: Medicare Prescription Drug Benefit Manual – Chapter 5

DATE: September 20, 2011

CMS is pleased to release updated Chapter 5 of the Medicare Prescription Drug Benefit Manual (Benefits and Beneficiary Protections). The revisions to Chapter 5 reflect changes previously released in the final regulations published in the Federal Register on April 15, 2010 and 2011 and in the Calendar Year 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter released on April 4, 2011.

Specifically, CMS:

- Added the definitions of "Applicable beneficiary," "Applicable drug," "Coverage Gap," and "Non-applicable drugs" to the definition section.
- Updated the description of Standard Prescription Drug Coverage and Alternative Prescription Drug Coverage to address coinsurance in the coverage gap.
- Clarified existing policy with respect to "Free first fill programs" by specifying that, for a new prescription, such programs must apply to both a beneficiary switch from a brand-name medication.
- Stipulated in the section Enhanced Alternative Gap Coverage that sponsors will no longer indicate their level of gap coverage in the Plan Benefit Package (PBP) software, but rather, CMS will quantify each plan's gap coverage and assign appropriate descriptions.
- Clarified existing policy in the section Restrictions on the Offering of Enhanced Alternative Coverage by MA Organizations to ensure that MA organizations offer at least one option for Part D coverage for supplemental premium at the cost of basic prescription drug coverage and announcing that two questions have been added to the PBP to help ensure this requirement is being met.
- Added a new section Coverage Gap Coinsurance.
- Clarified and updated existing policy regarding dispensing fees to reflect the long-term care dispensing requirements effective January 1, 2013.
- Updated the section Ensuring Meaningful Differences in Approved Bids to reflect that CMS will only approve a bid submitted by a sponsor if its plan benefit package or cost structure is meaningfully different from other plan offerings by the sponsor in the same service area with respect to key characteristics.

- Updated the section Meaningful Differences in Basic Prescription Drug Coverage Options to state that CMS believes that sponsors should only submit one basic offering for a stand-alone prescription drug plan in a service area.
- Updated the section Meaningful Differences in Enhanced Alternative Coverage Options to state that CMS will announce its meaningful differences evaluation methodology via the annual payment notice and call letter.
- Updated the section Transition Period for Sponsors or Parent Organizations with New Acquisitions to reflect a 2 year transition period.
- Updated the section Consolidated Renewal Plan to cover consolidation of two enhanced alternative plans.
- Updated the section PDP Plan Benefit Package (PBP) Renewal and Crosswalk Guidance to include a section Consolidated Plans under a Parent Organization.
- Added a new section Low Enrollment Plans.
- Added a new section Manufacturer Drug Discount Program.
- Updated the sections Costs that Count as Incurred Costs, Costs that do not Count as Incurred Costs, Summary of TrOOP-Eligible and TrOOP-Ineligible Payers, and Pharmacy Waiver/Reduction of Cost-Sharing and Applicability, by addressing discounts paid by manufacturers as part of the Medicare Coverage gap Discount program, costs paid by the Indian Health Service or an Indian tribe or organization, and costs paid by AIDS Drug Assistance Program.
- Clarified the section on Mail-Order Pharmacy Access to state that a pharmacy that makes some, but not all, deliveries by common carrier is not a mail order pharmacy.
- Clarified the section Level Playing Field Between Mail-Order and Retail Pharmacies by stating that the alternative retail/mail order pharmacy rate shall not cause the standard terms and conditions offered to similarly situated pharmacies to vary with respect to the any willing provider pharmacy provisions.
- Revised the section Out-of-Network Pharmacy Access to add an option for sponsors to create an out-of-network benefit structure.
- Clarified the section Public Disclosure of Pharmaceutical Prices for Equivalent Drugs to state that CMS may modify the timing requirement for informing enrollees of any differential between the price of a covered part D drug to an enrollee and the price of the lowest priced generic version if the requirement becomes impracticable to administer.
- Added an Electronic Transactions Standards section to address unique BIN/PCN provisions and Prescriber Identifiers.
- Updated Appendix 1: Adequate Access to Network Home Infusion Pharmacies by State/Territory and Contract Type with 2011 data.

The manual revisions are available at

http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp

Any questions regarding this manual chapter may be directed to Lisa Thorpe via e-mail at Lisa.Thorpe@cms.hhs.gov.