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

CENTER FOR MEDICARE

DATE: November 18, 2011

TO: All Medicare Advantage Organizations (MAPD) and Prescription Drug Plan (PDP) Sponsors

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

SUBJECT: Contract Year 2012 Monitoring of Marketed Comprehensive Formularies

Section 60.5.4 of the Medicare Marketing Guidelines in Chapter 3 of the Medicare Prescription Drug Benefit Manual includes CMS' requirements for formularies provided on plan websites.[1] Per the guidance in this section, Part D sponsors who provide prescription drugs must include (as PDF documents) their current formulary including tier level and any applicable quantity limit restrictions, prior authorization criteria and step therapy criteria on their website. In addition, plans must post utilization management documents for both step therapy and prior authorization criteria applied to each formulary drug. Consistent with the guidance in Chapter 3, Part D sponsors are required to ensure the accuracy of their marketing documents. However, based on Part D audit findings, self disclosed marketing errors, and beneficiary complaints, CMS is concerned that sufficient quality assurance is not being performed on the marketed formulary materials.

CMS also expects online formularies will reflect the most recently approved formulary file. In order to ensure the accuracy of marketed formulary documents, CMS is announcing an enhanced monitoring effort in which selected plan sponsors' marketed formularies will be compared to their HPMS approved formularies that are effective January 1, 2012. CMS will select a random sample of Part D plans for inclusion in the analysis. The sample selection will include MAPDs and PDPs, but will exclude employer-group plans, 800 series plans and PACE organizations. Part D sponsors that are selected for analysis will be notified and provided additional information this month.

The methodology described below is generally how CMS will complete this analysis. Comprehensive formulary and utilization management documents extracted from selected Part D sponsors' websites will be compared to the HPMS approved formulary that is effective January 1, 2012. For each marketed formulary, CMS will extract all the drug listings and their associated information, including the drug name and corresponding tier information and utilization management instructions. We will then match the extracted listings and corresponding information

[1] Part D formulary marketing requirements are provided in 42 CFR 423.128(d)(2)(ii) and Chapter 3 of the Medicare Prescription Drug Benefit Manual.

to the HPMS approved formulary. While drugs on the HPMS approved formulary contain standard identifiers (e.g. related brand name, related Semantic Clinical Drug Component (SCDC) containing the generic name and strength, related dosage form and a reference National Drug Code (NDC)), the marketed listings may only distinguish drugs by a few identifiers (e.g. brand or generic name and occasionally dosage, strength, and/or route). Where possible, we will match drugs by all four variables (i.e. brand name, generic name, strength and dosage form). Drugs whose marketed tier or utilization management (i.e. prior authorization, step therapy and/or quantity limit) indicator does not match the HPMS approved information will be flagged as potential discrepancies.

CMS contracted with Acumen, LLC to assist with marketed formulary extraction and data comparisons. Selected Part D plans will use a secure website, managed by Acumen, to view and respond to potential discrepancies. Data extraction is scheduled to occur during November and communications of potential discrepancies between the marketed formulary and the HPMS approved formulary communicated via Acumen's secure website are scheduled for December. The secure website will allow sponsors to download and upload responses to potential issues on the designated response forms. Medicare Compliance Officers of the selected plans will receive a notification that provides detailed instructions about accessing and designating access to the secure website.

As noted above, potential discrepancies between the marketed and HPMS approved formulary are scheduled for release via the secure website in December. It is CMS' expectation that selected Part D sponsors will work aggressively to correct any confirmed errors prior to January 1, 2012. Failure to correct confirmed errors prior to January 1, 2012 may subject your organization to a formal compliance action. For questions regarding the marketed versus approved analysis please contact Monica Reed (Monica.reed@cms.hhs.gov) or Jessica Herrera-Cancel (Jessica.herreracancel@cms.hhs.gov).