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

CENTER FOR MEDICARE

DATE: October 29, 2014

TO: All Part D Sponsors

FROM: Amy K. Larrick, Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Contract Year 2015 Monitoring of Marketed Comprehensive Formularies

42 C.F.R. §423.128 and Section 100.5 of the Medicare Marketing Guidelines (MMG) provide specific requirements for disseminating Part D information. Medicare Advantage Organizations, Medicare-Medicaid Plans (MMPs) and Prescription Drug Plan sponsors offering Part D (Part D sponsors) must include on their website their current formulary including tier level, limited access indicator and any applicable quantity limit restrictions, prior authorization and step therapy requirements. In addition, Part D sponsors must post utilization management documents for both step therapy and prior authorization criteria applied to each formulary drug.

The Centers for Medicare & Medicaid Services (CMS) expects that online formularies will reflect the most recently approved formulary file. In order to ensure the accuracy of marketed formulary documents, CMS will again be conducting a review comparing marketed formularies on plan websites for Contract Year 2015 to their HPMS-approved formularies that will be effective January 1, 2015. CMS will select a random sample of Part D plans for inclusion in the analysis, excluding PACE organizations. Please note that employer group waiver plans (EGWPs) and MMPs are eligible for inclusion in the analysis for CY 2015. However, regarding MMPs, this analysis will not address Additional Demonstration Drugs (ADDs). Part D sponsors that are selected for analysis will be notified and provided additional information.

CMS will extract comprehensive formulary and utilization management documents from plan websites and compare these to the HPMS-approved formulary effective January 1, 2015. For each marketed formulary, CMS will identify a sample of drugs listed with their associated information, including the drug name and corresponding tier information, limited access indicator and utilization management restrictions. We will then match the extracted listings and corresponding information to the HPMS-approved formulary. Drugs with a marketed tier, limited access or utilization management (i.e. prior authorization, step therapy and/or quantity limit) indicator that does not match the HPMS-approved information will be flagged as potential discrepancies. In addition to the review of samples, CMS will be reviewing online formulary and utilization management documents for compliance with the non-drug requirements identified in section 100.5 (e.g., indication of when the formulary documents were last updated including the phrase, "Updated MM/YYYY" or "No changes made since MM/YYYY").

CMS contracted with Acumen, LLC (Acumen) to assist with the marketed formulary extraction. Acumen will start contacting Part D plan sponsors for whom potential discrepancies are identified between the marketed and approved formularies within the next few weeks. Sponsors will be required to submit responses to potential issues on designated response forms. In addition, it is our expectation that selected Part D sponsors will work aggressively to correct any confirmed errors prior to January 1, 2015. Identified discrepancies between the marketed and HPMS-approved formulary may subject your organization to a formal compliance action.

For questions regarding the marketed versus approved analysis please contact Teisha Robertson (teisha.robertson@cms.hhs.gov) or Mariann Kocsis (mariann.kocsis@cms.hhs.gov).