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

CENTER FOR MEDICARE

DATE: November 1, 2013

TO: All Part D Sponsors

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

SUBJECT: Contract Year 2014 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 and Prescription Drug Plan sponsors offering Part D (Part D sponsors) must include their current formulary including tier level, limited access indicator and any applicable quantity limit restrictions, prior authorization and step therapy requirements on their website. In addition, plans must post utilization management documents for both step therapy and prior authorization criteria applied to each formulary drug.

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 2014 to their HPMS-approved formularies which will be effective January 1, 2014. CMS will select a random sample of Part D plans for inclusion in the analysis. The sample selection will include all Part D sponsors, but will exclude PACE organizations. Please note that employer group waiver plans (EGWPs) and Medicare-Medicaid Plans (MMPs) are eligible for inclusion in the analysis for CY 2014. 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, 2014. 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 within the next few weeks identifying potential discrepancies between the marketed formulary and the HPMS-approved formulary. Sponsors will be required to submit responses to potential issues on designated response forms.

As noted above, potential discrepancies between the marketed and HPMS-approved formulary are scheduled for release in November. It is our expectation that selected Part D sponsors will work aggressively to correct any confirmed errors prior to January 1, 2014. Failure to correct confirmed errors prior to January 1, 2014 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).