DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: October 26, 2015

TO: All Part D Sponsors

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

SUBJECT: Contract Year 2016 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. To that end, CMS evaluated whether Part D sponsors followed these requirements for Contract Year (CY) 2015 and intends to conduct this analysis again for CY 2016 Part D sponsors.

CY 2015 Results

In the October 29, 2014 Health Plan Management System (HPMS) memo entitled "Contract Year 2015 Monitoring of Marketed Comprehensive Formularies"; CMS announced that we would be conducting a review comparing marketed formularies on plan websites for CY 2015 to HPMS-approved formularies that would be effective January 1, 2015.

One hundred fifty-nine Part D contracts were selected for inclusion in the CY 2015 Monitoring of Marketed Comprehensive Formularies Analysis (MvA). We identified a targeted sample of drugs for review for each of the participating Part D plan contracts. After reviewing the marketed formularies on plan websites and analyzing the results, we determined that 18 out of the 159 Part D sponsors (11.3%) had discrepancies. The negatively marketed discrepancies included: plans associated with a Defined Standard (DS) benefit that marketed tiers in their posted formularies; plans marketing incorrect generic copays; and plans marketing more restrictive utilization management or limited access. In addition, we found discrepancies where plans did not include in their marketing document the phrase, "Updated MM/YYYY" or "No change made since

MM/YYYY" as noted in Section 100.5 of the Medicare Marketing Guidelines. Based on the discrepancies identified in the CY 2015 Monitoring of Marketed Comprehensive Formularies and the areas of non-compliance identified during the analysis, CMS continues to be concerned that sponsors are not appropriately marketing their formularies consistent with the HPMS-approved formularies, and as a result we will be repeating the analysis for CY 2016.

CY 2016 Monitoring

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 CY 2016 to their HPMS-approved formularies that will be effective January 1, 2016. CMS will select a 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 2016. However, regarding MMPs, this analysis will not address Additional Demonstration Drug (ADD) file drugs. 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, 2016. 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 (e.g., prior authorization, step therapy, 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 analysis. 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, 2016. Identified discrepancies between the marketed and HPMS-approved formularies may subject your organization to a formal compliance action.

For questions regarding the marketed versus approved analysis please contact Naseem Tarmohamed (naseem.tarmohamed@cms.hhs.gov) or Mariann Kocsis (mariann.kocsis@cms.hhs.gov).