DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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MEDICARE DRUG BENEFIT AND C & D DATA GROUP

DATE: October 24, 2016

TO: All Part D Sponsors

FROM: Amy Larrick Chavez-Valdez, Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Contract Year 2017 Monitoring of Marketed Comprehensive Formularies

Per 42 C.F.R. §423.128 and Section 100.5 of the Medicare Marketing Guidelines (MMG), there are 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 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) 2016 and intends to conduct this analysis again for CY 2017 Part D sponsors.

CY 2016 Results

In the October 23, 2015 Health Plan Management System (HPMS) memo entitled "Contract Year 2016 Monitoring of Marketed Comprehensive Formularies," CMS announced that we would be conducting a review comparing marketed formularies on plan websites for CY 2016 to CMS-approved HPMS formularies that would be effective January 1, 2016.

One hundred ninety Part D contracts were selected for inclusion in the CY 2016 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 7 out of the 190 Part D contracts (3.70 %) had discrepancies. The discrepancies included: plans marketing enhancements in error, plans marketing an incorrect tier in error, and plans with a drug missing from their marketed formulary. We also identified administrative errors such as plans failing to define an acronym used in a formulary legend and instances where plans did not include in their marketing document the phrase, "Updated MM/YYYY" or "No change made since MM/YYYY" as noted in

the Medicare Marketing Guidelines, Section 100.5 of the Medicare Prescription Drug Benefit Manual.

CY 2017 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 2017 to their approved formularies that will be effective January 1, 2017. CMS will select a random sample of Part D plans for inclusion in the analysis. Please note that employer group waiver plans (EGWPs) and MMPs are eligible for inclusion in the analysis for CY 2017. EGWPs that are selected but do not post a formulary will be required to provide their formulary via email to CMS at partdformularies@cms.hhs.gov. 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 CMS-approved formulary effective January 1, 2017. For each marketed formulary, CMS will identify a sample of drugs listed with their associated information, including the drug name and corresponding tier information, and utilization management restrictions. We will then match the extracted listings and corresponding information to the approved formulary. Drugs with a marketed tier or utilization management (e.g., prior authorization, step therapy, or quantity limit) indicator that does not match the 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, 2017. Identified discrepancies between the marketed and 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).