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

DATE: November 6, 2018

TO: All Part D Sponsors

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

SUBJECT: Correction - Contract Year 2019 Monitoring of Marketed Comprehensive Formularies

Requirements pertaining to the dissemination of Part D information are found at 42 C.F.R. §423.128. Additional guidance pertaining to the marketing of formularies was previously outlined in Sections 60.4 and 100.4 of the Medicare Marketing Guidelines (MMG). As communicated in the November 1, 2018 Health Plan Management System (HPMS) memorandum entitled "Part D Communication Materials," while some specific requirements do not appear in the updated Medicare Communications and Marketing Guidelines, this guidance still applies and will be incorporated into the Medicare Prescription Drug Benefit Manual in a future update. Part D sponsors must include on their website their current drug list or formulary, including tier level and any applicable quantity limit restrictions, prior authorization, and step therapy requirements. Part D sponsors must also post all step therapy and prior authorization utilization management criteria documents. CMS monitors the posting and accuracy of these formulary documents. This memorandum provides a summary of the results of CY 2018 monitoring and announces that this analysis will be performed again for CY 2019.

CY 2018 Results

In the October 24, 2017 HPMS memorandum entitled "Contract Year 2018 Monitoring of Marketed Comprehensive Formularies," CMS announced that we would be conducting a review comparing marketed formularies on plan websites for CY 2018 to CMS-approved HPMS formularies that would be effective January 1, 2018.

One hundred seventy-six Part D contracts were selected for inclusion in the CY 2018 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 of the 176 Part D contracts (10.23 %) had discrepancies. The discrepancies included: plans with a drug missing from their marketed formulary, plans marketing an incorrect tier in error, plans associated with a Defined Standard (DS) benefit that marketed tiers in their posted formularies, and plans marketing enhancements in error. We also identified administrative errors such as plans failing to define an indicator used to denote a restriction in the formulary, plans not including the

applicable HPMS approved formulary file submission ID number on their formulary, 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 Section 100.4 of the Medicare Marketing Guidelines.

CY 2019 Monitoring

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 2019 to their approved formularies within HPMS that will be effective January 1, 2019. CMS will select a random sample of Part D plans for inclusion in the analysis, excluding PACE organizations. In addition to the random selection, new sponsors and sponsors with previously identified marketed formulary concerns will be included. Employer Group Waiver Plans that are selected but do not post a formulary will be required to provide a PDF of their comprehensive formulary via email to CMS at PartDFormularies@cms.hhs.gov. Part D sponsors that are selected for the CY 2018 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, 2019. For each marketed formulary, CMS will identify a sample of drugs from the HPMS formulary file and match them to the posted formulary PDF. Missing drugs or drugs with a marketed tier or utilization management (e.g., prior authorization, step therapy, or quantity limit) indicator that is more restrictive than that contained on the HPMS formulary file will be deemed a discrepancy. In addition to the review of drug samples, CMS will be reviewing online formulary and utilization management documents for compliance with the non-drug requirements set forth in prior guidance (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 will provide Part D plan sponsors for whom discrepancies are identified a workbook containing the discrepancies. Sponsors will be required to submit responses to formulary discrepancies via designated response forms. In addition, it is our expectation that selected Part D sponsors will work aggressively to correct any confirmed errors as soon as possible. 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 and Mariann Kocsis at PartDFormularies@cms.hhs.gov