June 29, 2020

VIA ELECTRONIC SUBMISSION at www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-10185

RE: **Medicare Part D Reporting Requirements; CMS-10185 (OMB control number: 0938-0992)**

To Whom It May Concern:

Highmark Inc. ("Highmark") is one of America's leading health insurance organizations and an independent licensee of the Blue Cross and Blue Shield Association. Highmark, together with its Blue-branded affiliates, collectively comprises the fourth-largest Blue Cross and Blue Shield-affiliated organization and one of the nation's 10 largest health insurance organizations. Highmark and its affiliated health plans work passionately to deliver high-quality, accessible, understandable, and affordable experiences, outcomes, and solutions to customers in Pennsylvania, Delaware, and West Virginia.

We thank the Centers for Medicare & Medicaid Services ("the Department") for the opportunity to provide comment on the information collection request for CMS-10185, Medicare Part D Reporting Requirements.

The proposed changes to the "Section II: Medication Management Therapy Programs" appear to include references to updates to the CY2021 MTM program that had been proposed in the Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Proposed Rule ("2021 and 2022 MA/Part D Proposed Rule") yet not finalized in the corresponding Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program Final Rule ("2021 MA/Part D Final Rule"). CMS explained in the 2021 MA/Part D Final Rule that the proposed provisions from the CY2021 and 2022 MA/Part D Proposed Rule, which were not addressed in the Final Rule, would be addressed in a second final rule to be issued later in 2020, but would not become effective until at least January 1, 2022. We would like to request clarification regarding how CMS intends to treat the discrepancy between the current CY2021 MTM program requirements and the following proposed CY2021 Part D Reporting Requirements:

- **Element K:** Element K of the proposed Part D MTM reporting requirements directs plans to identify how a beneficiary had met their MTM program criteria, including via their designation as an at-risk beneficiary ("ARB") within the MA plan's Drug Management Program (DMP). The proposal to expand MTM eligibility criteria to

include ARBs was proposed in Section E. "Eligibility for Medication Therapy Management Programs (MTMPs)" of the 2021 and 2022 MA/Part D Proposed Rule but, as noted above, not finalized. The inclusion of ARBs in the MTM eligibility criteria was similarly not addressed in the May 22, 2020 HPMS memo titled "2021 Medication Therapy Management Program Information and Submission Instructions." We urge CMS to clarify this apparent discrepancy.

- **Element AA:** Element AA of the proposed Part D MTM reporting requirements directs plans to identify the "number of communications sent to beneficiary regarding safe disposal of medications," a directive that appears to be related to a provision in the 2021 and 2022 MA/Part D Proposed Rule, which had proposed a requirement Part D Sponsors provide this information to all beneficiaries enrolled in their MTM programs at least annually. As noted above, this provision was not addressed in the 2021 MA/Part D Final Rule, and therefore does not appear to be applicable to the CY2021 MTM program. We request CMS issue clarifying guidance to address this concern.

We thank the Department for consideration of our comments and requests.

Respectfully,

Amy M. Sawyer
Director Health Policy
Government Affairs
Highmark, Inc.
T: 412.554.2455
Email: Amy.WallaceSawyer@Highmark.com