

June 29, 2020

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Mr. Alex M. Azar, II, Secretary, Department of Health and Human Services

c/o Centers for Medicare & Medicaid Services,  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850.  
Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05,

**Title of Information Collection: Medicare Part D Reporting Requirements-  
OMB control number 0938-0992**

Dear Secretary Azar,

Envision Pharmaceutical Services, LLC (Envision) appreciates the opportunity to comment on the proposed Medicare Part D Reporting Requirements and collection of information entitled **Medicare Part D Reporting Requirements** (Reporting Requirements). Envision is a pass through, transparent PBM that supports many Part D Plan Sponsors. Envision agrees and supports the reporting obligations within the Reporting Requirements and requests additional clarification related to the proposed **Medicare and Medicaid Programs Contract Year 2021 and 2022 Policy Rule**<sup>1</sup> (the Proposed Rule) which promulgated the Reporting Requirements.

**I. Section II. Updates to Medication Therapy Management Programs under Title I, Part 423, Subpart D, § 423.153**

Within the Proposed Rule, CMS updated the requirements for the Medication Therapy Management (MTM) program<sup>2</sup> in two ways. Based on these requirements in the Proposed Rule, two new elements were added to the proposed MTM program annual reporting section for Contract Year 2021 within the Reporting Rules.<sup>3</sup> Specifically, the Proposed Rule<sup>4</sup> required (i) the inclusion of at-risk beneficiaries based on the Drug Management Program (DMP), which was thereafter reflected in the addition of element K of the Reporting Requirements; and (ii) the number of communications sent to beneficiaries regarding safe disposal of medications, which was subsequently reflected in the addition of element AA of the Reporting Requirements.

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<sup>1</sup> *Medicare and Medicaid Programs; 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*

<sup>2</sup> Section III. *Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. A. Mandatory Drug Management Programs (DMPs)* (§ 423.153)

<sup>3</sup> *MEDICARE PART D REPORTING REQUIREMENTS. Section II. Medication Therapy Management Programs.*

<sup>4</sup> Section III.B. *Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs)* (§ 423.100). "Under section 2006 of the SUPPORT Act, CMS is required to identify Part D beneficiaries with a history of opioid-related overdose (as defined by the Secretary), and such individuals must be included as PARBs for prescription drug abuse under a Part D plan's DMP. CMS is also required under this section to notify the sponsor of such identifications. In line with this requirement, we are proposing to modify the definition of "potential atrisk beneficiary" at § 423.100 to include a Part D eligible individual who is identified as having a history of opioid-related overdose, as we propose to define it."

However, Page 88875 of the **Medicare and Medicaid Programs Contract Year 2021 and 2022 Policy Final Rule** (the Final Rule) indicated that MTM program information would be finalized in the second release of the Final Rule<sup>5</sup>. CMS also suggested that items effective for Contract year 2021 but included in the second release of the Final Rule would be optional for 2021 and mandatory for 2022.<sup>6</sup>

A. **Questions**. To that end, Envision has the following three Questions:

- Are new elements K and AA required for Contract Year 2021 Medicare Part D Reporting?
- If yes, should Part D sponsors assume that the proposed details in Section III.B. of the Proposed Rule should be relied upon for the inclusion of elements K and AA of the Reporting Requirements?
- Is there additional detail that we should expect for either 2021 or 2022?

B. **Comment**: Depending on the answers to the above questions, Envision suggests that the new elements K and AA either be removed from the 2021 MTM program annual reporting requirements or made optional and included in the 2022 MTM program annual reporting requirements after additional or final guidance has been provided. This will allow for adequate time to include these new requirements within program processes. MTM software configuration will be required and as such an appropriate amount of time is needed in order to incorporate these elements into platforms for documentation and reporting.

## Conclusion,

We thank the Departments for the opportunity to provide comments on this important Proposed Rule. PBMs and Plan Sponsors support the Administration's efforts to provide meaningful price and cost-sharing information to enrollees and purchasers and the general public. If you need additional information, please contact me at

Sincerely,

DocuSigned by:  


Holly Miller, PharmD BCACP

Sr. Director of Clinical Product Development and Strategy

2181 E. Aurora Road Suite 201

Twinsburg, OH 44087

330-486-6457 (W)

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<sup>5</sup> Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program Final Rule (page 33875) "Requirements to be Addressed Later in 2020 ++ ...++ Mandatory Drug Management Programs (DMPs) (§ 423.153) ++ Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100) ++ Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153) and Information on the Safe Disposal of Prescription Drugs

<sup>6</sup> Final Rule. 33796. I. Executive Summary and Background A. Executive Summary 1. Purpose. CMS plans to make any provisions adopted in the subsequent, second final rule, although effective on or before January 1, 2021, applicable no earlier than January 1, 2022.