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

DATE: November 15, 2022

TO: Medicare Part D Prescription Drug Plan Sponsors in the Calendar Year 2023 Part D Senior Savings Model

FROM: Laura T. McWright, Deputy Director, Seamless Care Models Group, Center for Medicare and Medicaid Innovation

SUBJECT: Updated Waivers in Part D Senior Savings Model Contract Addendum Related to Recently Enacted Legislation

The Centers for Medicare and Medicaid Services (CMS) is issuing an updated set of waivers of Part D Program Requirements for the Part D Senior Savings Model related to recently enacted legislation[1] which changed underlying Medicare Part D statutory requirements for participating Medicare Part D Prescription Drug Plan Sponsors. The updated waivers are in part to ensure participating Part D Sponsor's cost-sharing on its Plan Selected Model Drugs under the terms of the Model remains a Part D supplemental benefit despite otherwise applicable changes to Part D coverage for insulin. The below text replaces Appendix 1 of the contract year 2023 Addendum To Contract For The Operation Of A Voluntary Medicare Prescription Drug Plan For Participation In The Part D Senior Savings Model (the "Addendum"). The waivers herein are effective and incorporated into the Addendum as a replacement to Appendix 1 upon issuance.

For questions, please contact PartDSavingsModel@cms.hhs.gov.

Updated Appendix 1 to the Addendum:

Appendix 1: Waivers of Part D Program Requirements

A. Pursuant to Section 1115A(d)(1) of the Act, in its sole discretion, CMS waives the Medicare Part D statutory and regulatory requirements enumerated in this Appendix 1 for purposes of the Model. These waivers are granted only to the extent necessary to implement the Model. CMS may modify or rescind any or all of these waivers at any time, in its sole discretion.

B. Waivers for Part D Sponsors that are Model Participants. The waivers identified in this Section B are for Part D sponsors participating in the Model. Each waiver in this Section B is: (1) each contingent on compliance with the terms and conditions of this Addendum, the Approved Proposal, and documents incorporated therein; (2) is granted to Part D Plan Sponsor only as to the Model PBPs and only to the extent necessary to implement the Model

[1] On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA, P.L. 117-169) into law.

in accordance with the Addendum and documents incorporated therein; and (3) is granted only for the term of this Addendum.

1. Special Rule for Supplemental Benefits. The following requirement of section 1860D-14A(c)(2) of the Act and 42 CFR § 423.2325(e): "where an applicable beneficiary has supplemental benefits with respect to applicable drugs under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in, the applicable beneficiary shall not be provided a discounted price for an applicable drug under this section until after such supplemental benefits have been applied with respect to the applicable drug." This will allow supplemental benefits to apply to the discounted price after the manufacturer coverage gap discount is applied to a Model Drug.

2. Low Income Cost Sharing Subsidy Calculation. 42 CFR § 423.329(d)(1) to the extent necessary to calculate the low-income cost-sharing subsidy for a Model Drug based on the cost sharing of the formulary tier(s) for the Model Drug without regard to any Model-Specific Supplemental Benefits for such drug.

3. Uniformity and Accessibility of Benefits and Cost Sharing as Supplemental Benefits: Section 1860D–2(a)-(c) of the Act, including without limitation Section 1860D-2(b)(9); and 42 CFR §§ 423.104(b)(2) and 423.265(c) to the extent necessary solely to permit Part D sponsors to offer Model-Specific Supplemental Benefits and Part D Rewards and Incentives (RI) to non-LIS enrollees only, subject to the terms of the Model. Model-Specific Supplemental Benefits consist of the cost-sharing on Model Drugs described at Article 3, Section C(2)(i) and offered as a supplemental benefit pursuant to this Addendum. Part D RI includes any program offer under this Model in compliance with Appendix 2.

4. Tiering Exceptions. 42 CFR § 423.578(a) to the extent necessary to permit Part D sponsors to exclude from their tiering exceptions process for Model PBPs any requests to apply Model-Specific Supplemental Benefits to any applicable drug that is, or contains, a drug classified as insulin in American Hospital Formulary Service (AHFS) Drug Information or the DRUGDEX Information System compendia.

5. Prohibition on Mid-year Benefit Enhancements. Requirements under Section 1860D-11, to the extent necessary solely to permit Part D sponsors to add Plan Selected Model Drugs at any time during the plan year, consistent with existing Part D formulary requirements.

C. Waiver for Part D Sponsors. The waivers identified in this Section C are for Part D sponsors, inclusive of Part D sponsors not participating in the Model, and is granted only for the duration of the Model.

1. Star Ratings for Part D plans. 42 CFR §§ 423.182-423.186 and 422.162-422.166 to the extent necessary to permit CMS to adjust the rules for calculating the Star Ratings for Part D sponsors participating in the PDSS Model to protect against a statistically significant negative impact to the Part C and Part D Star Ratings for MA-PDs and stand-alone PDPs that are not participating in the Model when the impact is directly attributable to participation in the Model;

2. Part D Bid and Payment Data. Section 1860D-15(f) of the Act is waived to the extent necessary to permit CMS to use Part D bid and payment data for purposes of conducting and evaluating the Model.