

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE & MEDICAID INNOVATION

DATE: September 12, 2022

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

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

SUBJECT: Updates to PDSS Model Communications and Marketing Guidelines
for Contract Year 2023

On August, 16, 2022, President Biden signed the Inflation Reduction Act of 2022 into law. While the law includes many changes to Medicare Part D, this memorandum is focused on updates required to PDSS Model Communications and Marketing to make people with Medicare aware of their benefits under Section 11406 (Appropriate Cost-Sharing for Covered Insulin Products Under Medicare Part D), which will go into effect on January 1, 2023, concurrent with the start of the third Contract Year (CY) of the Part D Senior Savings (PDSS) Model.

Consistent with the September 6, 2022 Health Plan Management System (HPMS) memorandum titled, “Updates to Part D Member Materials for CY 2023,” (September 6 HPMS memorandum) that PDSS-participating plans must comply with, we are requiring additional changes to certain CMS required materials specified at §§ 422.2267(e) and 423.2267(e) and plan websites as required under §§ 422.111(h)(2) and 423.128(d)(2) that have PDSS-specific language, and are updating the requirements in the [CY 2023 PDSS Communications and Marketing Guidance](#) to meet two goals:

- (1) to make sure enrollees understand how *together* Section 11406 of the Inflation Reduction Act of 2022 and the PDSS Model affect their Part D coverage; and
- (2) to make sure, pursuant to 42 CFR §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(1) and the Addendum to Contract for the Operation of a Voluntary Medicare Prescription Drug Plan for Participation in the Part D Senior Savings Model (the “Addendum”), that information pertaining to *both* Section 11406 and the PDSS Model that is provided to people with Medicare is accurate.

In addition, as we approach the Annual Enrollment Period (AEP), CMS wants to make sure that people with Medicare, *including those currently enrolled in plans participating in the PDSS Model*, are not confused by the information contained in communications materials that fall outside of those required under §§ 422.111(h)(2), 422.2267(e), 423.128(d)(2), and 423.2267(e). Therefore, Part D sponsors participating in the PDSS Model should review all communications,

as defined under §§ 422.2260 and 423.2260, not just the specific materials addressed in this memorandum or the September 6 HPMS memorandum to make sure, pursuant to §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(1), that information and guidance for enrollees related to coverage of insulin are accurate in light of the changes under Section 11406 of the Inflation Reduction Act of 2022 and the continuation of the PDSS Model in CY 2023.

The following information outlines the materials that must be created or updated *specific to the PDSS Model*, including instructions for the content and timing of updates. CMS encourages Part D sponsors participating in the PDSS Model to reach out to CMS with any questions and/or for technical assistance on the required updates, including related to the [CY 2023 PDSS Communications and Marketing Guidance](#), via the PDSS mailbox at PartDSavingsModel@cms.hhs.gov.

Notice to Current Enrollees who Use Insulin – By November 15, 2022, Part D sponsors participating in the PDSS Model must deliver to current enrollees who use insulin a separate summary of insulin benefits and coverage so that such enrollees are notified of insulin benefits and coverage for which they are eligible. The following sentences must be included in this notice (bolded formatting should remain):

- **Important Message About What You Pay for Insulin** – You won’t pay more than \$35 *[update the cost sharing amount, if lower than \$35]* for a one-month supply of each insulin product covered by our plan, no matter what cost-sharing tier it’s on *[plans may update the tiering language if some insulins will be available at a tier lower than \$35]* *[insert only if plan’s benefit design includes a deductible: , even if you haven’t paid your deductible]*.
- **Getting Help from Medicare** – **If you chose this plan because you were looking for insulin coverage at \$35 or less a month, it is important to know that you may have other options available to you for 2023 at even lower costs because of changes to the Medicare Part D program. Contact Medicare, at 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week for help comparing your options. TTY users should call 1-877-486-2048.**
- **Additional Resources to Help** – Please contact our Member Services number at *[insert member services phone number]* for additional information. (TTY users should call *[insert TTY number]*.) Hours are *[insert days and hours of operation]*.

Select Insulins – CMS is updating its requirement on page 2 of the [CY 2023 PDSS Communications and Marketing Guidance](#) for the use of the term, “Select Insulin.” Participating Part D sponsors must use the term, “Select Insulin” only to refer to the subset of insulin drugs on the plan’s formulary that are Plan-Selected Model drugs. If a sponsor determines that it is both less confusing and more accurate not to use the term, “Select Insulin,” at all, it may omit this term from the required PDSS Model materials after notifying CMS at the PartDSavingsModel@cms.hhs.gov email and confirming that the term will not be used in any communications or marketing materials that include PDSS Model-related language.

Evidence of Coverage (EOC), Annual Notice of Change (ANOC), Part D Formulary, Summary of Benefits (SB), and Websites – PDSS-participating plans must make the updates to the corresponding PDSS model materials as those outlined in the September 6 HPMS memorandum. In addition, for the ANOC, PDSS plans must also include the additional PDSS

specific language for the model as outlined below (highlighted in blue font). PDSS-participating plans must also follow the timing requirements set out in the September 6 HPMS memorandum for the EOC, ANOC, Part D Formulary, SB and Websites. **In addition, PDSS-participating plans must update other instances, as applicable, where these required materials include information or guidance related to the PDSS Model that is confusing or misleading in combination with the updates outlined in the September 6 HPMS memorandum.**

PDSS Model Language Specific to the ANOC – PDSS-participating plans must add the following language to their ANOCs:

- Under “SECTION 2 Changes to Benefits and Costs for Next Year,” subsection titled, “Changes to Prescription Drug Costs,” plans must update to include the following sentences (bolded formatting should remain), **including the additional language for PDSS-participating plans** (font color formatting should not remain) at the end of the subsection.
 - **Important Message About What You Pay for Insulin** - You won’t pay more than \$35 *[update the cost sharing amount, if lower than \$35]* for a one-month supply of each insulin product covered by our plan, no matter what cost-sharing tier it’s on *[plans may update the tiering language if some insulins will be available at a tier lower than \$35] [insert only if plan’s benefit design includes a deductible: , even if you haven’t paid your deductible].*
 - **Getting Help from Medicare - If you chose this plan because you were looking for insulin coverage at \$35 a month or less, it is important to know that you may have other options available to you for 2023 at even lower costs because of changes to the Medicare Part D program. Contact Medicare, at 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week for help comparing your options. TTY users should call 1-877-486-2048.**
 - **Additional Resources to Help** – Please contact our Member Services number at *[insert member services phone number]* for additional information. (TTY users should call *[insert TTY number].*) Hours are *[insert days and hours of operation].*

Other Communications – In addition to following the guidance in the September 6 HPMS memorandum for other communications, PDSS-participating plans must update other instances, as applicable, where information or guidance related to the PDSS Model is confusing or misleading in combination with the updates outlined in the September 6 HPMS memorandum.

General Information – Errata guidance and models for the EOC and ANOC can be found at: <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial>. The model Part D formulary and notice of formulary change can be found at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials>. The CY 2023 PDSS Communications and Marketing Guidance can be found at: <https://innovation.cms.gov/media/document/pdss-cy23-marketing-comms-guidance>.

Plans may combine the notice to current enrollees who use insulin, updates and errata into a single mailing, provided the applicable dates are met.

For CY 2023, Part D sponsors participating in the PDSS Model **must resubmit** any materials previously submitted to CMS through the HPMS marketing module that are edited based on the PDSS Model specific guidance set forth in this memorandum. Part D sponsors participating in the PDSS Model also **are required to submit** any errata, notices (including the notice to current enrollees who use insulin detailed in this memorandum), and/or addenda created for any of the materials mentioned in this memorandum based on the guidance set forth herein. Part D sponsors participating in the PDSS Model must package these materials in a single zip file and submit within the HPMS marketing module via “PDSS Updated Member Materials-CY2023” subcategory within the “Required” submission type between September 14, 2022 and November 15, 2022, subject to retrospective review. CMS may take a compliance action in connection with the material changes required in this memorandum if CMS determines the materials are inaccurate or misleading.

PDSS-participating Part D sponsors are also responsible for ensuring that their customer service representatives and agents are thoroughly familiar with plan-specific details and the Medicare rules that apply to specific products, including those related to the PDSS Model and the changes under Section 11406 of the Inflation Reduction Act of 2022. CMS also *strongly* encourages Part D sponsors participating in the PDSS Model to consider additional communication and outreach strategies to help beneficiaries who use insulin (and particularly, those in underserved communities¹) understand their best plan option that meets their needs, inclusive of insulin and other Part D drug coverage and cost-sharing.

Part D sponsors participating in the PDSS Model should not submit requests to reflect new benefit requirements in their bids that have been submitted for Contract Year 2023, or submit requests to correct their Plan Benefit Packages (PBPs) to reflect these new requirements.

For questions concerning the PDSS Model and required materials and enrollee communications, please contact PartDSavingsModel@cms.hhs.gov.

¹ Section 2(b) of [Executive Order 13985](#) defines “underserved communities” as referring to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified by the list in the preceding definition of “equity” that is in the Executive Order.