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DATE: September 6, 2022

TO: All Prescription Drug Plans, Medicare Advantage-Prescription Drug Plans,
and Section 1876 Cost Plans

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SUBJECT: Updates to Part D Member Materials 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 making people with Medicare aware of their benefits under two provisions, Sections 11401 (Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices Under Medicare Part D) and 11406 (Appropriate Cost-Sharing for Covered Insulin Products Under Medicare Part D), that will go into effect on January 1, 2023. To make sure enrollees understand how these changes affect their Part D coverage and to make sure, pursuant to 42 CFR §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(1), that information provided to people with Medicare pertaining to this benefit is accurate, we are requiring changes to certain CMS required materials specified at §§ 422.2267(e) and 423.2267(e), as well as to plan websites as required under §§ 422.111(h)(2) and 423.128(d)(2).

In addition, as we approach the Annual Enrollment Period (AEP), CMS wants to make sure that people with Medicare 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, plans should review all communications, as defined under §§ 422.2260 and 423.2260, and not just the specific materials addressed in this memorandum, to make sure information and guidance for enrollees related to coverage of insulin or vaccines are accurate in light of the changes under Sections 11401 and 11406 of the Inflation Reduction Act of 2022.

The following information outlines the materials that must be updated, including instructions for the content and timing of updates.

Evidence of Coverage (EOC) – Under §§ 422.2267(e)(1) and 423.2267(e)(1), plans are required to provide enrollees with their EOC by October 15th listing all of the benefits offered under the plan.

Required Updates for Part D plans (including MA-PDs and cost plans with Part D contracts):

- Replace the first paragraph under “Section 9 – Part D Vaccines. What you pay for depends on how and where you get them” with the following paragraph (bolded formatting should remain): **Important Message About What You Pay for Vaccines** - Our plan covers most Part D vaccines at no cost to you *[insert only if plan’s benefit design includes a deductible: , even if you haven’t paid your deductible]*. Call Member Services for more information.
- Insert the sentence below (bolded formatting should remain) at the end of the “What you pay for your Part D prescription drugs” chapter, under section 2.1 “What are the drug payment stages for *[insert 2023 plan name]* members?”: **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]*.
- Plans must also update other instances, as applicable, where information or guidance related to coverage of insulin or vaccines are inconsistent with the Part D benefits as outlined under Sections 11401 and 11406 of the Inflation Reduction Act of 2022.

Timing:

- EOCs delivered electronically, as permitted under §§ 422.2267(d)(2)(i) and 423.2267(d)(2)(i), must be updated before being made available to enrollees by October 15th.
- Hard copy EOCs, as defined under §§ 422.2267(d)(1) and 423.2267(d)(1), must be updated before they are mailed to enrollees by October 15th whenever possible. If updates to the hard copy EOC are not practicable – for example, if they have already been printed – the model EOC errata may be used to communicate the updated and accurate information until current stock of outdated EOC documents is depleted. Where applicable, EOC errata intended to fix inaccurate or inconsistent information or guidance related to coverage of insulin or vaccines must be received by the enrollees by November 15th.

Annual Notice of Change (ANOC) – Under §§ 422.2267(e)(3) and 423.2267(e)(3), plans are required to provide current enrollees with an ANOC no later than September 30th to notify enrollees of changes to their benefits that will take effect on January 1st.

Required Updates for Part D plans (including MA-PDs and cost plans with Part D contracts):

- 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 at the end of the subsection (bolded formatting should remain): **Important Message About What You Pay for Vaccines** - Our plan covers most Part D vaccines at no cost to you *[insert only if plan’s benefit design includes a deductible: , even if you haven’t paid your deductible]*. Call Member Services for more information.
- 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 sentence (bolded formatting should remain) at the end of the subsection (after the sentences for vaccines, as outlined above): **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]*.
- Plans must also update other instances, as applicable, where information or guidance related to coverage of insulin or vaccines are inconsistent with the Part D benefits as outlined under Sections 11401 and 11406 of the Inflation Reduction Act of 2022.

Timing:

- ANOCs delivered electronically, as permitted under §§ 422.2267(d)(2)(ii) and 423.2267(d)(2)(ii), must be updated before they are provided to enrollees by no later than September 30th.
- Hard copy ANOCs, as defined under §§ 422.2267(d)(1) and 423.2267(d)(1), must be updated before they are mailed to enrollees by September 30th whenever possible. If updates to the hard copy ANOC are not practicable – for example, if they have already been printed – plans may use the CY 2023 ANOC errata model until current stock is depleted. Where applicable, ANOC errata intended to fix inaccurate or inconsistent information or guidance related to coverage of insulin or vaccines must be delivered to enrollees, as outlined in the model errata instructions, by November 15th.

Part D Formulary – Under § 423.2267(e)(9), plans are required to provide current enrollees with a formulary by October 15th.

Required Updates for Part D plans (including MA-PDs and cost plans with Part D contracts):

- Plans must update the abridged and comprehensive formulary, as applicable, where information or guidance related to coverage of insulin or vaccines are

inconsistent with the Part D benefits as outlined under Sections 11401 and 11406 of the Inflation Reduction Act of 2022; **or**

- On the front cover of the abridged and comprehensive formulary, directly following the required paragraph beginning with “This abridged/comprehensive formulary...,” plans must update to include the following sentences (bolded formatting should remain):
 - **Important Message About What You Pay for Vaccines** - Our plan covers most Part D vaccines at no cost to you *[insert only if plan’s benefit design includes a deductible: , even if you haven’t paid your deductible]*. Call Member Services for more information.
 - **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]*.
- Please see the website guidance in the section of this memorandum on required updates to searchable formularies.

Timing:

- Formularies delivered electronically, as permitted under §§ 422.2267(d)(2)(i) and 423.2267(d)(2)(i), must be updated before they are made available to enrollees by October 15th.
- Hard copy formularies, as defined under §§ 422.2267(d)(1) and 423.2267(d)(1), must be updated before they are mailed to enrollees by October 15th. If updates to the hard copy formularies are not practicable – for example, if they have already been printed – plans may send enrollees a notice of formulary change that reflects any changes to the formulary necessary to fix inaccurate or inconsistent information or guidance related to coverage of insulin or vaccines until current formulary stock is depleted. Enrollees must receive the notice of formulary change by November 15th.

Summary of Benefits (SB) – Under §§ 422.2267(e)(5) and 423.2267(e)(5), plans are required to include an SB with an enrollment form.

Required Updates for Part D plans (including MA-PDs and cost plans with Part D contracts):

- Plans must update their SB, as applicable, where information or guidance related to coverage of insulin or vaccines are inconsistent with the Part D benefits in Sections 11401 and 11406 of the Inflation Reduction Act of 2022.

Timing:

- Electronic SBs, as required under §§ 422.2267(e)(5)(i)(B) and 423.2267(e)(5)(i)(B), must be updated, as needed, before they are made available, no later than October 15th.
- Hard copy SBs, as required under §§ 422.2267(e)(5)(i)(A) and 423.2267(e)(5)(i)(A), must be updated, as needed, before they are included with an enrollment form. If SBs need to be updated, but have already been printed, plans are permitted to use an addendum to fix inaccurate or inconsistent information or guidance related to coverage of insulin or vaccines in conjunction with the SB until current stock is depleted.

Websites – Under §§ 422.111(h)(2) and 423.128(d)(2), plans are required to have an internet website.

Required Updates for Part D plans (including MA-PDs and cost plans with Part D contracts):

- Required website content, as defined under §§ 422.2265(b) and 423.2265(b), must be updated, as needed, where information or guidance related to coverage of insulin or vaccines are inconsistent with the Part D benefits as outlined under Sections 11401 and 11406 of the Inflation Reduction Act of 2022.
- Plans must update the required searchable formulary, as defined under §§ 422.2265(b)(5) and 423.2265(b)(5), to **either**:
 - Reflect the appropriate benefits as outlined under Sections 11401 and 11406 of the Inflation Reduction Act of 2022; **or**
 - Prominently include – for example, as a header, footer, or pop up – the following sentences:
 - **Important Message About What You Pay for Vaccines** - Our plan covers most Part D vaccines at no cost to you *[insert only if plan's benefit design includes a deductible: , even if you haven't paid your deductible]*. Call Member Services for more information.
 - **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]*.
- Those required posted materials, as defined under §§ 422.2265(c) and 423.2265(c), that are specifically mentioned in this memorandum must be updated in accordance with these instructions.
- Plans must update other instances, as applicable, where information or guidance related to coverage of insulin or vaccines are inconsistent with the Part D benefits as outlined under Sections 11401 and 11406 of the Inflation Reduction Act of 2022 in required materials, as defined under §§ 422.2265(c) and 423.2265(c), that are not specifically mentioned in this memorandum.

Timing:

- Website content and materials must be updated by October 15th.

Other Communications – As provided by under §§ 422.2262(a)(1) and 423.2262(a)(1), plans must make sure that their statements and the terminology used in communications activities and materials do not provide information that is inaccurate or misleading. Accordingly, plans should review all communications, as defined under §§ 422.2260 and 423.2260, where information or guidance related to coverage of insulin or vaccines are mentioned, and make updates as needed, to ensure they are not inconsistent with the Part D benefits as outlined under Sections 11401 and 11406 of the Inflation Reduction Act of 2022.

Part D Senior Savings (PDSS) Model – The PDSS Model will continue in the 2023 plan year. Required changes to the vaccine language in this memorandum apply to 2023 PDSS participating plan materials. A future HPMS memorandum will provide PDSS plans information on Model requirements applicable to plan communications and marketing of Model benefits and coverage for insulin.

General information – Model ANOC and EOCs, as well as errata guidance and models for each, 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>.

Plans may combine updates and errata into a single mailing, provided the applicable dates established in this memorandum are followed and the requirements for the multi-language insert (MLI) at §§ 422.2267(e)(31) and 423.2267(e)(33) are met. For the 2023 plan year, plans are not required to resubmit any materials previously submitted to CMS through the HPMS marketing module, as required under §§ 422.2261(a)(1) and 423.2261(a)(1), that are edited based on the guidance set forth in this memorandum. Plans also are not required to resubmit any errata, notices, or addenda created for any of the materials mentioned in this memorandum based on the guidance set forth herein. CMS will not take any compliance action for the material changes required in this memorandum.

Part D sponsors should not submit requests to reflect these new requirements in their bids that have been submitted for CY 2023, or submit requests to correct their Plan Benefit Packages (PBPs) to reflect these new requirements. A future HPMS memorandum will provide CY 2023 program guidance related to the Inflation Reduction Act changes to Part D coverage of vaccines and insulin.

For questions concerning the insulin and vaccine policy changes, please contact PartDPolicy@cms.hhs.gov. For questions concerning required materials and enrollee communications, please contact marketing@cms.hhs.gov.