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CENTERS FOR MEDICARE & MEDICAID SERVICES

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TO: All Part D Sponsors

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SUBJECT: Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin

The purpose of this memorandum is to provide Part D sponsors with guidance for implementing section 11401 (Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices under Medicare Part D) and section 11406 (Appropriate Cost Sharing for Covered Insulin Products under Medicare Part D) of the Inflation Reduction Act (IRA, P.L. 117-169[1]), enacted on August 16, 2022. These changes become effective January 1, 2023 and apply to all Part D plans, including Employer Group Waiver plans. This guidance is specific to Contract Year (CY) 2023. Separate guidance regarding future contract years will be issued at a later date.

Contract Year 2023 Plan Bids, including Formularies

Part D sponsors should not submit requests to reflect the new vaccine and insulin requirements in their bids that have already been submitted and approved for CY 2023. New section 1860D-15(h) of the Social Security Act (the Act) provides a temporary retrospective subsidy for plan year 2023 in an amount equal to the aggregate reduction in cost sharing and deductible due to the application of the new requirements under sections 1860D-2(b)(8) and (9) of the Act. As specified in section 1860D-2(b)(4)(C) of the Act, the temporary retrospective subsidy counts as incurred costs toward Part D enrollees' progression into the catastrophic phase. Part D sponsors also should not submit requests to correct their Plan Benefit Packages (PBPs) – including cost sharing, tiering structure, or both – to reflect these new requirements via the Plan Correction Module. Additionally, the cost of the aggregate reduction in cost sharing and deductible for which the temporary retrospective

[1] https://www.congress.gov/bill/117th-congress/house-bill/5376/text

subsidy created by the IRA is paid by Medicare does not meet the definition of allowable risk corridor costs provided at section 1860D-15(e)(1)(B) of the Act and § 423.308. Part D sponsors are not expected to update their formularies based on these new requirements, and any changes should be submitted only if they are in accordance with existing formulary update policy.

Medicare Plan Finder

The CY 2023 Medicare Plan Finder (MPF) will reflect Part D sponsors' insulin and vaccine benefits and cost sharing as they were submitted in their 2023 bid and formulary submissions. For October 1, 2022, CMS is updating MPF to include new insulin and vaccine drug footnotes and other help features to explain the benefit changes resulting from the IRA.

Requirements Applicable to Section 11401 (Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices under Medicare Part D)

Section 11401 of the IRA amends section 1860D-2 of the Act by adding paragraphs (b)(8) and (c)(5) and making other conforming amendments to require that, effective for plan years beginning on or after January 1, 2023, the deductible shall not apply to, and there is no cost sharing for, an adult vaccine recommended by the Advisory Committee on Immunization Practices (ACIP). Section 1860D-2(b)(8)(B) of the Act specifies that for purposes of section 1860D-2(b)(8) of the Act, the term "adult vaccine recommended by [ACIP]" means a covered Part D drug that is a vaccine licensed by the US Food and Drug Administration (FDA) under section 351 of the Public Health Service Act (PHSA) for use by adult populations and administered in accordance with recommendations of ACIP.

CMS interprets "adult vaccine" and "vaccine … for use by adult populations," solely for the purposes of section 1860D-2(b)(8) of the Act, to refer to those vaccines licensed by the FDA and recommended by ACIP for use in "adults," as described by the CDC/ACIP in the Adult Immunization Schedule[2] or other applicable ACIP recommendations. We also interpret the term "recommended" to mean all categories of ACIP recommendations, including those that are specified as based on shared clinical decision-making.

We note that the ACIP Vaccine Recommendations and Guidelines[3] also provide recommendations for use in limited populations and circumstances for certain other vaccines that are not on the CDC/ACIP Adult Immunization Schedule for routine immunization. We interpret the requirements of section 1860D-2(b)(8) of the Act also to apply to vaccines provided in such limited populations and circumstances, when used for adults in accordance with ACIP recommendations.

Part D vaccines are not subject to the requirements of section 1860D-2(b)(8) of the Act if they are (1) not recommended by ACIP for use in adults, or (2) administered to an individual who is not an adult, even if such use is supported by ACIP recommendations (e.g., according to the CDC/ACIP child and adolescent immunization schedule[4]). For example, certain Meningococcal

[2] https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html
[3] https://www.cdc.gov/vaccines/hcp/acip-recs/index.html
[4] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

ACWY vaccines, which are recommended for use in both children and adults, when administered to an individual aged 18 or younger, would not be subject to the requirements of section 1860D-2(b)(8) of the Act. Such vaccines are not eligible for the temporary retrospective subsidy for plan year 2023, and the cost sharing should be as reflected in the approved CY 2023 bid.

Generally, Part D vaccines that have ACIP-recommended uses in the adult population and are being used for an adult must be provided with no enrollee cost sharing. There is no enrollee cost sharing on the ingredient cost of the vaccine submitted on the prescription drug event (PDE) record, or any associated sales tax, dispensing fee, or vaccine administration fee, regardless of tier placement or benefit phase. CMS does not expect Part D sponsors to implement new prior authorization (PA) requirements on vaccines that were already submitted on approved formularies for CY 2023 to determine if their use is in accordance with ACIP recommendations. CMS will use information from the PDE record to calculate the amount of the retrospective subsidy.

Please refer to the Health Plan Management System (HPMS) memorandum released on September 26, 2022 titled "Prescription Drug Event Reporting Instructions for the Implementation of the Statutory Cost Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023" for more detailed examples.

New Part D vaccines that become available during the plan year and have an ACIP-recommended use in the adult population are subject to the cost-sharing requirements of section 1860D-2(b)(8) of the Act, regardless of whether a Part D sponsor adds such vaccines to the formulary midyear or the enrollee obtains the vaccine via a formulary exception. The ACIP holds three regular meetings in February, June, and October of each year, in addition to emergency sessions.[5] The purpose of these meetings is to review scientific data and vote on vaccine recommendations. If ACIP issues a new vaccine recommendation for use in adults during the plan year, Part D sponsors must apply the cost-sharing requirements of section 1860D-2(b)(8) of the Act to any applicable vaccine claims with dates of service after the issuance of such recommendation.

Requirements Applicable to Section 11406 (Appropriate Cost Sharing for Covered Insulin Products under Medicare Part D)

Section 11406 of the IRA amends section 1860D-2 of the Act by adding paragraphs (b)(9) and (c)(6) and making other conforming amendments to require that, effective for plan years beginning on or after January 1, 2023, the deductible shall not apply to covered insulin products, and cost sharing for a one-month supply of each covered insulin product must not exceed $35 for all enrollees in all coverage phases. Part D sponsors should make every effort to implement the cost-sharing limits by January 1, 2023. However, if a Part D sponsor is unable to do so and charges higher cost sharing between January 1, 2023 through March 31, 2023 based on its previously approved CY 2023 PBP, the plan must reimburse enrollees within 30 calendar days any cost-sharing amount charged to the enrollee that exceeds $35 for a one-month supply of a

[5] https://www.cdc.gov/vaccines/acip/meetings/index.html

covered insulin product. There is no such allowance beyond March 31, 2023. We note that existing formulary requirements under § 423.120(b) regarding formulary review and approval for insulin products otherwise remain unchanged for CY 2023.

Covered Insulin Products

Section 11406 defines "covered insulin product" at new paragraph (b)(9)(C) of section 1860D-2 of the Act as an insulin product that is a part D drug covered under the prescription drug plan or MA-PD plan, approved under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) or licensed under section 351 of the PHSA and marketed pursuant to such approval or licensure, including any covered insulin product that has been deemed to be licensed under section 351 of the PHSA pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and marketed pursuant to such section.

Covered insulin products are insulin products that are included on a Part D sponsor's formulary, treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal, or covered under the transition process in accordance with § 423.120(b)(3) and obtained at a network pharmacy or an out-of-network pharmacy in accordance with § 423.124(a) and (c). These include any new insulin products that become available during the plan year.

The term "insulin product," for purposes of section 1860D-2(b)(9) of the Act, means a product that contains insulin, including combination products that contain more than one type of insulin. In addition, "insulin product" includes a combination product that contains both insulin and a non-insulin drug or biological product. Medical supplies associated with the injection of an insulin product, when such supplies do not contain insulin and are not approved under section 505 of the FFDCA or licensed under section 351 of the PHSA, are not subject to the requirements of section 1860D-2(b)(9) of the Act.

Cost sharing on the ingredient cost submitted on the PDE record for a covered insulin product, and any associated sales tax or dispensing fee, must not exceed $35 for the plan-defined one-month supply as entered in the PBP (one-month supply). Part D sponsors must charge the applicable cost sharing under their approved CY 2023 PBP or $35, whichever is less, regardless of tier placement (i.e., the $35 cap applies to all tiers) or benefit phase. CMS will use information from the PDE record to calculate the amount of the retrospective subsidy.

Please refer to the HPMS memorandum released on September 26, 2022 titled "Prescription Drug Event Reporting Instructions for the Implementation of the Statutory Cost Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023" for more detailed examples.

For dispensing increments that are less than a one-month supply or more than a one-month supply, Part D sponsors will treat the $35 limit like a copay for purposes of determining the appropriate cost sharing. Part D sponsors are not required to prorate the $35 copay if less than a one-month supply is dispensed because insulin is not a solid oral dosage form subject to daily cost-sharing requirements at § 423.153(b)(4). For extended-day supplies (i.e., more than one-

month supply), cost sharing must not exceed $70 for up to a two-month supply or $105 for up to a three-month supply.

Requirements Applicable to Both Section 11401 (Vaccines) and Section 11406 (Insulin) Provisions

Plan Cost Sharing Equal to or Less than Statutory Limits

If cost sharing under the Part D sponsor's approved CY 2023 PBP is equal to $0 for vaccines, or equal to or less than $35 for a one-month supply of a covered insulin product, the enrollee would pay the plan cost sharing (if any), and the Part D sponsor would receive no temporary retrospective subsidy.

To the extent that a Part D sponsor's approved CY 2023 PBP reflects cost sharing (either as a copayment or coinsurance) for a vaccine or covered insulin product that is less than the 25 percent coinsurance provided under Defined Standard coverage, the Part D sponsor assumes the cost of that additional coverage. Only the difference between the plan cost sharing and the statutory limit of $0 for an ACIP-recommended vaccine or $35 for a one-month supply of a covered insulin product is eligible for the temporary retrospective subsidy.

The same principles apply in the event that the Part D sponsor's approved CY 2023 PBP reflects a complete or partial reduction in the deductible for an ACIP-recommended vaccine or a covered insulin product. For example, if the CY 2023 PBP eliminates the deductible for a vaccine or a covered insulin product, the cost of that additional coverage would be borne by the Part D sponsor as assumed in the plan bid, and a temporary retrospective subsidy would be available only to the extent necessary to reduce the cost sharing that would have applied under the Part D sponsor's approved CY 2023 PBP to $0 for an ACIP-recommended vaccine or $35 for a one-month supply of a covered insulin product. If the Part D sponsor's CY 2023 PBP partly reduces the deductible for an ACIP-recommended vaccine or a covered insulin product, the cost of that reduction would be borne by the Part D sponsor as assumed in the plan bid, and a temporary retrospective subsidy would be available only to reduce the amount paid by the beneficiary in the partial deductible to $0 for an ACIP-recommended vaccine or $35 for a one-month supply of a covered insulin product and, to the extent necessary, to reduce the cost sharing that would have applied under the Part D sponsor's approved CY 2023 PBP after the deductible to $0 for an ACIP-recommended vaccine or $35 for a one-month supply of a covered insulin product.

Out-of-Network Claims

Cost sharing must not exceed $0 for an ACIP-recommended adult vaccine or $35 for a one-month supply of a covered insulin product when provided by an out-of-network (OON) provider in accordance with § 423.124(a) and (c). Consequently, Part D sponsors may not charge an enrollee for any differential between the OON price and the plan allowance if it would result in cost sharing greater than these statutory limits. If the plan allowance for a covered insulin product obtained from the OON provider is less than $35, Part D sponsors may require non-LIS enrollees to pay a portion of, or all of, the differential between the OON provider's usual and customary price and the plan allowance, but in no event may a plan require an enrollee to pay more than $35

in total cost sharing for a one-month supply of a covered insulin product, inclusive of any OON differential charged to the enrollee. The temporary retrospective subsidy will pay for any OON differential that an enrollee would otherwise have paid for a vaccine or covered insulin product obtained from an OON provider if the $35 limit on cost sharing for a one-month supply of covered insulin products did not apply.

Low Income Subsidy (LIS) and Temporary Retrospective Subsidy

The low-income cost-sharing subsidy (LICS) pays for any difference between the applicable LIS enrollee cost sharing prior to the application of the IRA limits and the plan's cost sharing submitted with its approved CY 2023 PBP. If the applicable LIS cost sharing is greater than the IRA limits, the temporary retrospective subsidy pays this difference. Therefore, the temporary retrospective subsidy is available for any applicable LIS cost sharing that exceeds $0 for ACIP-recommended vaccines and any applicable LIS cost sharing that exceeds $35 (e.g., LIS Category 4) but is less than the plan's cost sharing, as reflected in the CY 2023 PBP, for covered insulin products.

Please refer to the HPMS memorandum released on September 26, 2022 titled "Prescription Drug Event Reporting Instructions for the Implementation of the Statutory Cost Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023" for more detailed examples.

Coverage Gap Discounts

Part D sponsors will continue to determine coverage gap discounts in accordance with existing rules for basic and enhanced alternative plans as assumed in the plan's approved CY 2023 bid. If the Part D sponsor's approved CY 2023 PBP reflects a reduction in cost sharing for ACIP-recommended vaccines or covered insulin products in the coverage gap as a supplemental benefit, the coverage gap discount and beneficiary cost sharing will be calculated after the application of said supplemental benefit, and a temporary retrospective subsidy will be available only to the extent necessary to reduce the enrollee's cost to $0 for an ACIP-recommended vaccine as required under section 1860D-2(b)(8) of the Act or $35 for a month's supply of a covered insulin product as required under section 1860D-2(b)(9) of the Act. If the Part D sponsor's approved CY 2023 PBP does not reflect a reduction in cost sharing for such vaccines or covered insulin products in the coverage gap, the coverage gap discount and beneficiary cost sharing will be calculated based on the negotiated price of the drug and a temporary retrospective subsidy will be available as described above.

Please refer to the HPMS memorandum released on September 26, 2022 titled "Prescription Drug Event Reporting Instructions for the Implementation of the Statutory Cost Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023" for more detailed examples.

Special Enrollment Period

Since MPF will reflect Part D sponsors' insulin benefits and cost sharing as they were submitted in their CY 2023 bids, CMS is granting a Special Enrollment Period (SEP) for Exceptional Circumstances to allow beneficiaries to add, drop, or change their Part D coverage if they find a better option after the 2022 Annual Enrollment Period (AEP) and through the end of 2023. This SEP will be available for all beneficiaries who use a covered insulin product and begins on December 8th, 2022 and ends on December 31, 2023. Beneficiaries may use this SEP one time during this period. To utilize this SEP, beneficiaries must call 1-800-MEDICARE so a customer service representative can process the enrollment change. Consistent with current policy, when Part D enrollees change plans mid-year, their True Out-of-Pocket (TrOOP) costs carry over from one plan to the next.

Part D Senior Savings (PDSS) Model

Part D Sponsors participating in the PDSS Model for CY 2023 should follow all guidance and requirements set forth in this memorandum unless otherwise specified in PDSS Model-specific guidance. Additional guidance specific to PDSS plans will be forthcoming.

Questions concerning this memorandum may be directed to PartDPolicy@cms.hhs.gov. Questions specific to the temporary retrospective subsidy may be directed to PDE-Operations@cms.hhs.gov.