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CENTER FOR MEDICARE

DATE: November 17, 2023

TO: Pharmaceutical Manufacturers; All Part D Plan Sponsors

FROM: Jennifer R. Shapiro, Director,
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SUBJECT: Medicare Part D Manufacturer Discount Program: Methodology for
Identifying Specified Manufacturers and Specified Small Manufacturers

The Inflation Reduction Act of 2022, Public L. 117-169 (IRA), established the Medicare Part D Manufacturer Discount Program (Discount Program) that begins on January 1, 2025. Under section 1860D-14C of the Social Security Act (the Act), added by section 11201 of the IRA, *applicable drugs* dispensed to *applicable beneficiaries* will be subject to *manufacturer discounts* both in the initial and catastrophic coverage phases of the Part D benefit. For certain manufacturers' *applicable drugs* marketed as of August 16, 2022,¹ the IRA provides for lower *applicable discounts* during a multi-year phase-in period, which concludes by 2031 when such *applicable drugs* will be subject to the full amount of the discounts. Under section 1860D-14C(g)(4) of the Act, there are two such phase-ins: the Specified Manufacturer Phase-In and the Specified Small Manufacturer Phase-In.

On November 17, 2023, CMS issued through the Health Plan Management System (HPMS) a memorandum titled "Medicare Part D Manufacturer Discount Program Final Guidance" (the guidance) which discusses the phase-in eligibility criteria, discount percentages and schedule for the two Discount Program phase-ins. This memorandum explains the methodology CMS will use to identify manufacturers that qualify for the phased-in discounts. Terms are defined in Appendix 1 and italicized in this memorandum upon their first use.

¹ As discussed in section 50.1 of the Medicare Part D Manufacturer Discount Program Final Guidance, for purposes of identifying applicable drugs of specified manufacturers and specified small manufacturers that are subject to phase-ins, CMS interprets the reference to a drug that "is marketed as of the date of enactment [August 16, 2022]" in sections 1860D-14C(g)(4)(B)(i) and 1860D-14C(g)(4)(C)(i) of the Act, to refer to a drug that was marketed by the manufacturer on one specific, backward-looking date, i.e., the date of enactment of the IRA. Accordingly, for purposes of identifying applicable drugs of specified manufacturers and specified small manufacturers subject to phase-ins, CMS will determine whether an applicable drug had Part D expenditures on or before August 16, 2022, and did not have a marketing end date on the FDA NDC SPL Data Elements File before August 17, 2022.

Background

1. Specified Manufacturer Phase-In

The specified manufacturer phase-in applies to applicable drugs of specified manufacturers that are marketed as of August 16, 2022, and dispensed to applicable beneficiaries who are Low-Income Subsidy (LIS) eligible under section 1860D-14(a) of the Act. Pursuant to section 1860D-14C(g)(4)(B)(ii) of the Act, and consistent with section 50.1.1 of the guidance, a specified manufacturer is a manufacturer of an applicable drug that, in 2021, had:

1. A Coverage Gap Discount Program agreement in effect (a manufacturer that participated in the Coverage Gap Discount Program in 2021 by means of an arrangement whereby its labeler code(s) was/were listed on another manufacturer's Coverage Gap Discount Program agreement would be considered to have had an agreement in effect during 2021); **and**
2. *Total expenditures* for all its *specified drugs* covered by such Coverage Gap Discount Program agreement(s) for 2021, and covered under Part D in 2021, represented less than 1.0 percent of total expenditures for all *Part D drugs* in 2021; **and**
3. Total expenditures for all its specified drugs that are single source drugs and biological products for which payment may be made under Part B during 2021 represented less than 1.0 percent of the total expenditures for all drugs or biologicals under Part B in 2021.

2. Specified Small Manufacturer Phase-In

The specified small manufacturer phase-in applies to applicable drugs of specified small manufacturers that are marketed as of August 16, 2022, and are dispensed to applicable beneficiaries. Pursuant to section 1860D-14C(g)(4)(C)(ii) of the Act, and consistent with section 50.1.2 of the guidance, a specified small manufacturer is a manufacturer of an applicable drug that, in 2021:

1. Is a specified manufacturer; **and**
2. Had total expenditures under Part D for any one of its *specified small manufacturer drugs* covered under a Coverage Gap Discount Program agreement(s) for 2021, and covered under Part D in 2021, equal to or greater than 80 percent of the total expenditures for all of its specified small manufacturer drugs covered under Part D in 2021.

3. Aggregation Rule

As required by section 1860D-14C(g)(4)(B)(ii)(II)(bb) of the Act for specified manufacturers and section 1860D-14C(g)(4)(C)(ii)(II)(bb) of the Act for specified small manufacturers, all entities, including corporations, partnerships, proprietorships, and other entities treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 are treated as one manufacturer (the "same manufacturer") for purposes of identifying the manufacturers eligible for each phase-in.

Any manufacturer that meets the definition of a specified or specified small manufacturer, but is acquired after 2021 by a manufacturer that does not meet such definition (i.e., the specified or specified small manufacturer becomes part of such acquiring manufacturer) is not included in the definition (i.e., is no longer eligible for the applicable phase-in), effective at the beginning of the

plan year immediately following the acquisition or, for an acquisition before 2025, effective January 1, 2025.

As discussed in section 50.2 of the guidance and pursuant to the terms of the Discount Program agreement, for purposes of implementing this aggregation rule, CMS requires participating manufacturers to submit and attest to the required ownership information in HPMS. The required manufacturer ownership information is discussed in more detail in Appendix A of the Part D Manufacturer Discount Program Information Collection Request (ICR), CMS-10846 (OMB control no. 0938-1451), which is approved by the Office of Management and Budget (OMB) through September 30, 2025.² See section 80.5 of the guidance for more information on requirements related to reporting and maintenance of required information, including corporate ownership and information about labeler codes assigned by the FDA to the manufacturer or otherwise covered by its Discount Program agreement.

Because we do not currently prohibit a participating manufacturer from covering by its Discount Program agreement labeler code(s) assigned by the FDA to another manufacturer, the manufacturer must determine which labeler codes under each P number are attributable to the same manufacturer, and also determine if there are any labeler codes under different P numbers which also are attributable to the same manufacturer. To apply the aggregation rule, CMS will evaluate the ownership information submitted by manufacturers and determine which labeler codes, including, if any, labeler codes listed under different P numbers, must be attributed to and aggregated under the same manufacturer.

Methodology

In this section, we describe how CMS will calculate the three values needed for determining which manufacturers that had a Coverage Gap Discount Program agreement in 2021 are specified manufacturers and specified small manufacturers. The three values are:

- The manufacturer's percent share of Part D total expenditures
- The manufacturer's percent share of Part B total expenditures
- Each drug's percent share of the specified manufacturer's Part D total expenditures

A. Calculating the Manufacturer's Percent Share of Part D Total Expenditures

The first value that needs to be determined is each manufacturer's share of Part D total expenditures, which will be used to determine if the manufacturer's total expenditures for all of its applicable drugs covered under a Coverage Gap Discount Program agreement(s) for 2021, and covered under Part D in 2021, represented less than 1.0 percent of total expenditures for all Part D drugs in 2021. CMS will identify manufacturers that meet this threshold for the specified manufacturer phase-in by first summing the 2021 Part D total expenditures for Part D drugs, then summing the 2021 Part D total expenditures for applicable drugs for each manufacturer, and finally, identifying each manufacturer for which 2021 Part D total expenditures for applicable drugs are less than 1.0 percent of all 2021 Part D total expenditures.

² https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202307-0938-003

Step 1: Calculating the Part D total expenditures for 2021

CMS calculated the Part D total expenditures for 2021 reported on all final action,³ non-delete Prescription Drug Event (PDE) records submitted as of June 30, 2022, which represents the annual PDE data submission deadline for Part D payment reconciliation, for all Part D drugs dispensed in Benefit Year 2021. This value represents the Part D total expenditures and will be used as the denominator when calculating the percent share of Part D total expenditures attributable to each manufacturer's applicable drugs in step 3 below.

Step 2: Calculating each manufacturer's Part D total expenditures for applicable drugs for 2021

For purposes of calculating each manufacturer's Part D total expenditures for applicable drugs, CMS will identify the *National Drug Codes (NDCs)* attributable to the manufacturer that have a Marketing Category Code of 'NDA', 'BLA', or 'NDA AUTHORIZED GENERIC' on the NDC SPL Data Elements (NSDE) File maintained by the Food and Drug Administration (FDA). CMS will attribute an NDC as reported on the PDE record to the manufacturer using the *labeler code* extracted from the first 5 digits of each NDC.

CMS will calculate the Part D total expenditures for each relevant NDC attributable to the manufacturer as reported on all final action, non-delete PDE records submitted as of June 30, 2022 for applicable drugs dispensed in Benefit Year 2021.

CMS will then sum the Part D total expenditures for all relevant NDCs attributable to the manufacturer; that is, the Part D total expenditures for all applicable drugs of all manufacturers treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, as identified by the ownership information submitted and attested to by the manufacturer (as described above in the Aggregation Rule).

Step 3: Calculating each manufacturer's percent share of Part D total expenditures for 2021

CMS will divide the Part D total expenditures for applicable drugs of the manufacturer, determined in step 2 above, by the Part D total expenditures for all Part D drugs, determined in step 1 above, and then multiply by 100 to get the manufacturer's percent share.

If a manufacturer's Part D total expenditures for its applicable drugs are less than 1.0 percent of the 2021 Part D total expenditures, CMS will consider the manufacturer to have satisfied the Part D total expenditure criterion for specified manufacturer phase-in eligibility.

B. Calculating the Manufacturer's Percent Share of Part B Total Expenditures

The next value that needs to be determined is each manufacturer's share of Part B total expenditures, which will be used to determine if the manufacturer's total expenditures for all of its specified drugs that are single source drugs or biological products represented less than 1.0 percent of the total expenditures for all drugs or biologicals under Part B in 2021, excluding expenditures for a drug or biological that are bundled or packaged into payment for another service. This calculation involves three steps: identifying 2021 Part B total expenditures for

³ CMS uses the term "final action" to describe the most recently accepted original, adjustment, or delete PDE record representing a single dispensing event. See the 2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide, page 3-29, available at [https://www.csscooperations.com/internet/csscw3.nsf/DIDC/FJUKANFCP1~Prescription%20Drug%20Program%20\(Part%20D\)~Training](https://www.csscooperations.com/internet/csscw3.nsf/DIDC/FJUKANFCP1~Prescription%20Drug%20Program%20(Part%20D)~Training)

drugs and biological products, identifying the 2021 Part B total expenditures for single-source drugs and biological products for each manufacturer that had a Coverage Gap Discount Program agreement(s) in 2021, and identifying eligible manufacturers for which Part B total expenditures for single source drugs or biological products represent less than 1.0 percent of total expenditures for drug and biological products under Part B for 2021.

Step 1: Calculating Part B total expenditures for all drugs and biological products for 2021

CMS will identify all Healthcare Common Procedure Coding System (HCPCS) codes for drugs and biological products. Then, CMS will calculate Part B Carrier, durable medical equipment (DME), and Outpatient Medicare Part B total expenditures for drug and biological products for Fee-for-Service claim line items with a drug- or biological product-related HCPCS code, submitted as of December 31, 2022, which represents the Medicare Fee-For-Service submission deadline for calendar year 2021.

Step 2: Calculating each manufacturer's Part B total expenditures for applicable drugs that are single-source drugs and biological products for 2021

CMS will first map the HCPCS codes identified in step 1 above to NDCs using the NDC-HCPCS Crosswalk file provided as part of the CMS ASP Pricing File and the Pricing, Data Analysis and Coding (PDAC) HCPCS to NDC crosswalk file. Since the ASP NDC-HCPCS Crosswalk file is not a comprehensive list of all drugs/NDCs available in the United States, a Medi-Span Generic Product Identifier (GPI-14) expansion is used to help identify all NDCs associated with the HCPCS codes. We define a single source drug following the definition in section 1847A(c)(6)(D) of the Act and we are identifying NDCs for single source drugs using Medi-Span and the FDA NSDE marketing category data, or biological products using the FDA Purple Book. A HCPCS code is considered to be indicative of a single source drug or biological product if each NDC associated with the HCPCS code is for a single source drug or biological product. The corresponding NDCs are used to determine the labeler codes for each applicable HCPCS code. CMS will match the labeler code extracted from the first 5 digits of each NDC to the manufacturer. (See Aggregation Rule)

Since a HCPCS code can be mapped to multiple NDCs and labeler codes, it can also be associated with multiple manufacturers. While Part B single source drugs or biological products can be mapped to a particular HCPCS code, mapping applicable Part B expenditures to a particular manufacturer when a particular HCPCS code may reflect drugs of multiple manufacturers can be challenging. For this reason, CMS will only count the payments associated with a HCPCS code toward a manufacturer's 2021 Part B total expenditures if the HCPCS code is only mapped to drugs of that same manufacturer consistent with the Aggregation Rule.

Step 3: Calculating each manufacturer's percent share of Part B total expenditures for 2021

CMS will divide the Part B total expenditures for the applicable drugs that are single source drugs and biological products of the manufacturer, determined in step 2 above, by the Part B total expenditures for all drugs and biological products, determined in step 1 above, and then multiply by 100 to get the manufacturer's percent share.

If a manufacturer's Part B total expenditures are less than 1.0 percent of the 2021 Part B total expenditures, CMS will consider the manufacturer to have satisfied the Part B total expenditure criterion for the specified manufacturer phase-in eligibility.

C. Calculating Each Drug's Percent Share of the Specified Manufacturer's Part D Total Expenditures for Applicable Drugs

The last value that needs to be determined for each specified manufacturer is the total expenditures under Part D for any one of the manufacturer's specified drugs covered under a Coverage Gap Discount Program agreement(s) for 2021, and covered under Part D in 2021, which will be used to determine if the manufacturer's total expenditures for one specified drug are equal to or greater than 80 percent of the total expenditures for all of its specified drugs covered under Part D in 2021 such that the manufacturer is eligible for the specified small manufacturer phase-in.

Step 1: Aggregate all NDCs for applicable drugs reported on PDEs for each specified manufacturer that have the same active moiety for drug products, or same active ingredient for biological products, and with the same holder of the NDA/BLA

In order to determine one drug's share of a manufacturer's Part D total expenditures, which we will use to identify specified small manufacturers, we first note that for drug products, one specified small manufacturer drug will include all dosage forms and strengths of a drug with the same active moiety and the same holder of the New Drug Application (NDA),⁴ inclusive of products that are marketed pursuant to different NDAs. For biological products, one specified small manufacturer drug will include all dosage forms and strengths of the biological product with the same active ingredient and the same holder of the Biologic Licensing Application (BLA),⁵ inclusive of products that are marketed pursuant to different BLAs. CMS will identify the holder of the NDA/BLA for a drug or biological product as reported in Drugs@FDA or FDA Purple Book.

If a drug is a fixed combination drug⁶ with two or more active moieties/active ingredients, the distinct combination of active moieties/active ingredients will be considered as one active moiety/active ingredient for the purpose of identifying a specified small manufacturer drug. Therefore, all formulations of this distinct combination with the same NDA/BLA holder will be aggregated across all dosage forms and strengths of the fixed combination drug. A product containing only one (but not both) of the active moieties/active ingredients with the same NDA/BLA holder will not be aggregated with the formulations of the fixed combination drug and will be considered a separate specified small manufacturer drug.

CMS will attribute Part D expenditures for a drug, including authorized generic drugs and repackaged and relabeled drugs, to a specified manufacturer based on the NDC(s) for the drug, as reported on PDE records. Specifically, CMS will match the labeler code extracted from the first 5 digits of each NDC to the manufacturer. (See Aggregation Rule)

Step 2: Calculate the Part D total expenditures for each aggregated drug for 2021

CMS will calculate the Part D total expenditures for each aggregated drug attributable to the manufacturer as identified in step 1 by summing the Part D total expenditures for all NDCs under

⁴ As described in section 505(c) of the FD&C Act.

⁵ As described in section 351(a) of the PHS Act.

⁶ As described in 21 C.F.R. § 300.50.

each aggregated drug as reported on all final action, non-delete PDE records submitted as of June 30, 2022, for drugs dispensed in Benefit Year 2021.

Step 3: Calculate each drug's percent share of the specified manufacturer's Part D total expenditures for applicable drugs for 2021

CMS will divide the Part D total expenditures for each aggregated drug, determined in step 2 of this section, by the Part D total expenditures for all applicable drugs of the specified manufacturer, determined in section A, step 2 above, and then multiply by 100 to get the percent share.

Specified manufacturers that have 2021 Part D total expenditures for a single specified drug that are equal to or greater than 80 percent of the specified manufacturer's Part D total expenditures for all specified drugs are considered to have met the eligibility criteria for specified small manufacturers and are eligible for the specified small manufacturer phase-in.

Appendix 1: Definitions

Applicable beneficiary means an individual who, on the *date of dispensing* a Part D drug:

- (1) Is enrolled in a prescription drug plan or an MA-PD plan;
- (2) Is not enrolled in a qualified retiree prescription drug plan; and
- (3) Has incurred costs, as determined in accordance with section 1860D-2(b)(4)(C) of the Act, for Part D drugs in the year that exceed the annual deductible specified in section 1860D-2(b)(1) of the Act.

Applicable discount has the meaning set forth in section 50 of the Manufacturer Discount Program Final Guidance.

Applicable drug means a Part D drug that is:

- (1)
 - (i) Approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA); or
 - (ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act; and
- (2)
 - (i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in;
 - (ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in; or
 - (iii) Is provided to a particular applicable beneficiary through an exception

or appeal for that applicable beneficiary; and

- (3) Does not include a selected drug (as defined in section 1192(c) of the Act) during a price applicability period (as defined in section 1191(b)(2) of the Act) with respect to such drug.

Covered Part D drug has the meaning set forth at 42 CFR § 423.100.

Date of dispensing means the date of service. For long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement.

Labeler code means the first segment of the NDC that identifies a particular manufacturer.

Manufacturer means any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. For purposes of the Part D Manufacturer Discount Program, such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law, but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with the Food and Drug Administration (FDA) identifying the product's manufacturer, product and package size and type.

Part D drug has the meaning set forth at 42 CFR § 423.100.

P Number is the unique identifier established by CMS for each participating manufacturer.

Specified drug means, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by a specified manufacturer.

Specified small manufacturer drug means, for 2021, any applicable drug that is produced, prepared, propagated, compounded, converted, or processed by a specified small manufacturer.

Total expenditures means —

- (1) With respect to Part D, the total gross covered prescription drug costs, as defined in section 1860D-15(b)(3) of the Act; and
- (2) With respect to Part B, the total Medicare allowed amount (i.e., total allowed charges), inclusive of beneficiary cost sharing, for Part B drugs and biologicals, except that expenditures for a drug or biological that are bundled or packaged into the payment for another service are excluded.