Compliance Analysis Report

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INQUIRY

> Our parent company holds a 45% equity stake in a Joint Venture (JV) that sells a separate Part D portfolio. The JV has $3B in sales. We have $100M. Does this 45% ownership trigger the 'Aggregation Rule' under IRC Section 52(a) or (b) as referenced in the IRA? Specifically, what is the exact percentage threshold for a 'Controlled Group' of corporations that would force us to aggregate our sales with the JV and lose our 'Specified Small Manufacturer' status?

ANALYSIS

Under the Medicare Part D Manufacturer Discount Program (MDP), the "Aggregation Rule" for determining eligibility for the "Specified Small Manufacturer" phase-in status is governed by Social Security Act Section 1860D-14C(g)(4)(B)(ii)(II)(bb) and Section 1860D-14C(g)(4)(C)(ii)(II)(bb) 1. These statutory provisions explicitly mandate that CMS treat as a single manufacturer all entities that are treated as a single employer under subsection (a) or (b) of Section 52 of the Internal Revenue Code (IRC) of 1986 1.

Controlled Group Percentage Threshold

The exact percentage threshold for a "Controlled Group" under IRC Section 52(a) and (b) is generally more than 50% [8].

IRC 52(a) refers to a "controlled group of corporations" as defined in IRC 1563(a), but with a critical modification: the standard "at least 80%" voting power or value requirement is replaced by a "more than 50%" threshold for the purposes of these aggregation rules [8].

IRC 52(b) applies similar "more than 50%" control standards to un-incorporated trades or businesses (partnerships, proprietorships, etc.) under common control 5.

Impact of Your 45% Equity Stake

Based on the "more than 50%" threshold:

Aggregation Trigger: A 45% equity stake in a Joint Venture (JV) typically falls below the "more than 50%" threshold required to form a controlled group under IRC Section 52, provided there are no other overlapping ownership structures or constructive ownership rules that would push the total control above 50% [8].

Financial Exposure: If the entities are not aggregated, your $100M in sales would be evaluated independently of the JV's $3B in sales. To qualify as a "Specified Small Manufacturer," a manufacturer must first meet the "Specified Manufacturer" criteria (total 2021 Part D expenditures < 1.0% of all Part D expenditures) AND have one drug account for 80% of its own Part D expenditures in 2021 5.

- Risk of Loss of Status: If CMS determines that aggregation is required (e.g., through broader "common control" definitions or HPMS ownership attestations), the combined $3.1B in sales would likely exceed the 1.0%

expenditure threshold, disqualifying both entities from the phase-in 2.

Compliance Requirements

Manufacturers were required to submit and attest to detailed ownership information in the Health Plan Management System (HPMS) by December 8, 2023, to receive a preliminary eligibility determination 1. CMS uses this data, along with Medicare Part B and Part D PDE data, to make final determinations [3]. If you have been acquired by a non-specified manufacturer after 2021, you lose your status effective the following plan year (or January 1, 2025, for earlier acquisitions) 4.

SUPPORTING SOURCES (9 Citations)

1 CMS Medicare Part D Manufacturer Discount Program - Implementation Guidance

CMS Medicare Part D Manufacturer Discount Program - Implementation Guidance > CENTER FOR MEDICARE > B. Final Guidance > 50 - Applicable Discounts > 50.2 - Determination Of Phase-In Eligibility

50.2 - Determination of Phase-In Eligibility

For purposes of identifying manufacturers eligible for phase-ins, the aggregation rule at section 1860D-14C(g)(4)(B)(ii)(II)(bb) of the Act for specified manufacturers and section 1860D14C(g)(4)(C)(ii)(II)(bb) of the Act for specified small manufacturers requires that CMS treat as a single manufacturer all entities that are treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, and requires that manufacturers provide and attest to necessary information as specified by CMS. Because CMS does not have information about which entities are treated as a single employer under the Internal Revenue Code, manufacturers that wish to participate in the Discount Program must submit information about the company and its products in order for CMS to make a determination about phase-in eligibility. The required information must be submitted through HPMS (see sections 80.3 and 80.5.1 of this guidance for more information).

Additional operational instructions related to the submission of required ownership information in HPMS can be found in the November 17, 2023 HPMS memorandum entitled 'Instructions for Submitting Required Ownership Information for the Medicare Part D Manufacturer Discount Program; Opportunity to Receive Preliminary Information About Status as a Specified Manufacturer and Specified Small Manufacturer for 2025'.

2 CMS Medicare Part D Manufacturer Discount Program - Implementation Guidance

CMS Medicare Part D Manufacturer Discount Program - Implementation Guidance > CENTER FOR MEDICARE > B. Final Guidance > 50 - Applicable Discounts > 50.1 - Phase-In Of Applicable Discounts > 50.1.1 - Phase-In For Specified Manufacturers > Specified Manufacturer

Specified Manufacturer

Pursuant to section 1860D-14C(g)(4)(B)(ii) of the Act, a specified manufacturer is a manufacturer of an applicable drug that, in 2021 had:
- A Coverage Gap Discount Program agreement in effect; 9
- Total expenditures for all of its specified drugs (as defined in section 130 of this guidance) 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
- Total expenditures for all of its specified drugs that are single source drugs and biological products for which payment may be made under Part B in 2021 represented less than 1.0 percent of the total expenditures under Part B for all drugs or biological products in 2021.

Pursuant to the aggregation rule set forth in section 1860D-14C(g)(4)(B)(ii)(II)(bb) of the Act, 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 for purposes of this section.

3 CMS Medicare Part D Manufacturer Discount Program - Implementation Guidance

CMS Medicare Part D Manufacturer Discount Program - Implementation Guidance > CENTER FOR MEDICARE > B. Final Guidance > 50 - Applicable Discounts > 50.2 - Determination Of Phase-In Eligibility

50.2 - Determination of Phase-In Eligibility

CMS will identify which manufacturers qualify for these phase-ins by analyzing Medicare Part B claims data, Part D PDE data, and ownership information submitted by manufacturers. All manufacturers that sign a Discount Program agreement in time to participate in any year of the phase-in will be considered, and do not need to submit a separate application.

A detailed description of the methodology CMS will use to identify manufacturers eligible for phase-ins is provided in the November 17, 2023 HPMS memorandum entitled 'Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and

Specified Small Manufacturers'. Included in the methodology is a description of the data sources and calculations CMS will use for determining each manufacturer's eligibility for the two Discount Program phase-ins.

4 CMS Medicare Part D Manufacturer Discount Program - Implementation Guidance

CMS Medicare Part D Manufacturer Discount Program - Implementation Guidance > CENTER FOR MEDICARE > B. Final Guidance > 50 - Applicable Discounts > 50.1 - Phase-In Of Applicable Discounts > 50.1.1 - Phase-In For Specified Manufacturers > Specified Manufacturer

Specified Manufacturer

Any manufacturer that otherwise meets the definition of a specified manufacturer that is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer (i.e., the specified manufacturer becomes part of such acquiring manufacturer) is not included in the definition of specified manufacturer, effective at the beginning of the plan year immediately following the acquisition or, for an acquisition before 2025, effective January 1, 2025.

5 CMS Medicare Part D Manufacturer Discount Program - Implementation Guidance

CMS Medicare Part D Manufacturer Discount Program - Implementation Guidance > CENTER FOR MEDICARE > B. Final Guidance > 50 - Applicable Discounts > 50.1 - Phase-In Of Applicable Discounts > 50.1.2 - Phase-In For Specified Small Manufacturers > Specified Small Manufacturer

Specified Small Manufacturer

Pursuant to section 1860D-14C(g)(4)(C)(ii) of the Act, a specified small manufacturer is a manufacturer of an applicable drug that, in 2021:
- Is a specified manufacturer as described in section 50.1.1 of this guidance; and
- The total expenditures under Part D for any one of its specified small manufacturer drugs (as described in section 130 of this guidance) covered under a Coverage Gap Discount Program agreement(s) for 2021 and covered under Part D in 2021 are equal to or greater than 80 percent of the total expenditures for all its specified small manufacturer drugs covered under Part D in 2021.

Pursuant to the aggregation rule set forth in section 1860D-14C(g)(4)(C)(ii)(II)(bb) of the Act, 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 for purposes of this section.

Any manufacturer that otherwise meets the definition of a specified small manufacturer that is acquired after 2021 by another manufacturer that does not meet the definition of a specified small manufacturer (i.e., the specified small manufacturer becomes part of such acquiring manufacturer) is not included in the definition of specified small manufacturer, effective at the beginning of the plan year immediately following the acquisition or, for an acquisition before 2025, effective January 1, 2025.

6 Inflation Reduction Act - Medicare Drug Pricing Provisions

Inflation Reduction Act - Medicare Drug Pricing Provisions > TITLE I-COMMITTEE ON FINANCE > Subtitle B-Prescription Drug Pricing Reform > PART 3 - PART D IMPROVEMENTS AND MAXIMUM OUT-OF-POCKET CAP FOR MEDICARE BENEFICIARIES > SEC. 11201. MEDICARE PART D BENEFIT REDESIGN. > SEC. 1860D-14C. MANUFACTURER DISCOUNT PROGRAM.

SEC. 1860D-14C. MANUFACTURER DISCOUNT PROGRAM.

(aa) the manufacturer had a coverage gap discount agreement under section 1860D-14A;
(bb) the total expenditures for all of the specified drugs of the manufacturer covered by such agreement or agreements for such year and covered under this part during such year represented less than 1.0 percent of the total expenditures under this part for all covered Part D drugs during such year; and
(cc) the total expenditures for all of the specified drugs of the manufacturer that are single source drugs and biological products for which payment may be made under part B during such year represented less than 1.0 percent of the total expenditures under part B for all drugs or biological products for which payment may be made under such part during such year.
(II) SPECIFIED DRUGS.-
(aa) IN GENERAL.-For purposes of this clause, the term 'specified drug' means, with respect to a specified manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer.
(bb) AGGREGATION RULE.-All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this subparagraph. For purposes of making a determination pursuant to the previous sentence, an agreement under this section shall require that a manufacturer provide and attest to such information as specified by the Secretary as necessary.
(III) LIMITATION.-The term 'specified manufacturer' shall not include a manufacturer

7 Inflation Reduction Act - Medicare Drug Pricing Provisions

Inflation Reduction Act - Medicare Drug Pricing Provisions > TITLE I-COMMITTEE ON FINANCE > Subtitle B-Prescription Drug Pricing Reform > PART 3 - PART D IMPROVEMENTS AND MAXIMUM OUT-OF-POCKET CAP FOR MEDICARE BENEFICIARIES > SEC. 11201. MEDICARE PART D BENEFIT REDESIGN. > SEC. 1860D-14C. MANUFACTURER DISCOUNT PROGRAM.

SEC. 1860D-14C. MANUFACTURER DISCOUNT PROGRAM.

(i) IN GENERAL.-In the case of an applicable drug of a specified small manufacturer (as defined in clause (ii)) that is marketed as of the date of enactment of this subparagraph and dispensed for an applicable beneficiary, the term 'discounted price' means the specified small manufacturer percent (as defined in clause (iii)) of the negotiated price of the applicable drug of the manufacturer.
(ii) SPECIFIED SMALL MANUFACTURER.-
(I) IN GENERAL.-In this subparagraph, subject to subclause (III), the term 'specified small manufacturer' means a manufacturer of an applicable drug for which, in 2021-
(aa) the manufacturer is a specified manufacturer (as defined in subparagraph (B)(ii)); and
(bb) the total expenditures under part D for any one of the specified small manufacturer drugs of the manufacturer that are covered by the agreement or agreements under section 1860D-14A of such manufacturer for such year and covered under this part during such year are equal to or more than 80 percent of the total expenditures under this part for all specified small manufacturer drugs of the manufacturer that are covered by such agreement or agreements for such year and covered under this part during such year.
(II) SPECIFIED SMALL MANUFACTURER DRUGS.-
(aa) IN GENERAL.-For purposes of this clause, the term 'specified small manufacturer drugs' means, with respect to a specified small manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer.

8 Inflation Reduction Act - Medicare Drug Pricing Provisions

Inflation Reduction Act - Medicare Drug Pricing Provisions > TITLE I-COMMITTEE ON FINANCE > Subtitle B-Prescription Drug Pricing Reform > PART 1-LOWERING PRICES THROUGH DRUG PRICE NEGOTIATION > SEC. 11002. SPECIAL RULE TO DELAY SELECTION AND NEGOTIATION OF BIOLOGICS FOR BIOSIMILAR MARKET ENTRY.

SEC. 11002. SPECIAL RULE TO DELAY SELECTION AND NEGOTIATION OF BIOLOGICS FOR BIOSIMILAR MARKET ENTRY.

(aa) The manufacturing schedule for such biosimilar biological product submitted to the Food and Drug Administration during its review of the application under such section 351(k).
(bb) Disclosures (in filings by the manufacturer of such biosimilar biological product with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of such biosimilar biological product, or comparable documentation that is distributed to the shareholders of privately held companies.
(C) AGGREGATION RULE.-
(i) IN GENERAL.-All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, or in a partnership, shall be treated as one manufacturer for purposes of paragraph (2)(D)(iv).
(ii) PARTNERSHIP DEFINED.-In clause (i), the term 'partnership' means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the manufacturer of the biological product and the manufacturer of the biosimilar biological product.
(2) RULES DESCRIBED.-The rules described in this paragraph are the following:

9 CMS Medicare Part D Manufacturer Discount Program - Implementation Guidance

CMS Medicare Part D Manufacturer Discount Program - Implementation Guidance > CENTER FOR MEDICARE > B. Final Guidance > 80 - Requirements For Participating Manufacturers > 80.5 - Reporting And Maintenance Of Required Information > 80.5.1 - Corporate Ownership

80.5.1 - Corporate Ownership

As discussed in section 50.2, CMS will identify which participating manufacturers are specified manufacturers and specified small manufacturers for purposes of applying the phased-in discounts. In order to make an accurate determination, CMS will rely on ownership information provided and attested to in HPMS by manufacturers that submit all required information. As discussed in section 50.2.1 of this guidance, for the first year of the Discount Program, CMS will provide manufacturers that submit and attest to all required ownership information by December 8, 2023, without executing a Discount Program agreement, with preliminary, non-binding information regarding their eligibility for the phase-ins. The specific data CMS requires from all participating manufacturers for purposes of making determinations about phase-in eligibility is available as an attachment to the ICR (CMS-10846, OMB control no. 0938-1451), which is approved by OMB through September 30, 2025.

Participating manufacturers are required to notify CMS of a change in ownership within 30 calendar days after the manufacturers execute a legal obligation for such an arrangement and no later than 45 calendar days prior to the change in ownership taking effect.