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CENTER FOR MEDICARE

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TO: Pharmaceutical Manufacturers; All Part D Plan Sponsors

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SUBJECT: Medicare Part D Manufacturer Discount Program: Frequently Asked Questions

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. Since publication of the Medicare Part D Manufacturer Discount Program Final Guidance and the Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers on November 17, 2023, CMS has received technical questions from manufacturers, Part D sponsors, and other interested parties regarding the policies and methodologies described in those documents. The attached document is intended to provide clarifying responses to those questions.

Medicare Part D Manufacturer Discount Program: Frequently Asked Questions

Last Updated April 19, 2024

CMS will update this list of Frequently Asked Questions (FAQs) as needed to provide information to interested parties.

Question: Section 1860D-14C of the Social Security Act (the Act) provides for lower applicable discounts for certain manufacturers' applicable drugs marketed as of August 16, 2022 during a multi-year phase-in period which concludes in 2031. Under section 1860D-14C(g)(4) of the Act, there are two such phase-ins: one for certain applicable drugs of specified manufacturers dispensed to applicable beneficiaries who are eligible for the low-income subsidy (LIS) under section 1860D-14(a) of the Act and one for certain applicable drugs of specified small manufacturers dispensed to all applicable beneficiaries. CMS noted in section 50.2 of the Medicare Part D Manufacturer Discount Program Final Guidance[1] (Final Guidance) that it would provide additional information to assist Part D sponsors with identifying National Drug Codes (NDCs) that are eligible for the phase-in discounts after Discount Program agreements are executed. What additional information will CMS provide, and when?

Answer: To facilitate uniform and accurate application of the specified manufacturer and specified small manufacturer phase-in discounts across the Part D program, CMS will publish periodically, but no less frequently than monthly starting in December 2024, a list of all 9-digit NDCs (NDC-9s) that are eligible for the specified manufacturer or specified small manufacturer phase-ins (NDC list). For each NDC-9 that appears in the NDC list, Part D sponsors will identify all 11-digit NDCs (NDC-11s) associated with each NDC-9 using the FDA NDC SPL Data Elements (NSDE) File and apply the applicable phase-in discounts to each NDC-11. An initial NDC list will be released in late Spring 2024, and an updated list will be released in December 2024.

On April 4, 2024, CMS published a list of all participating labeler codes that will be covered under a Discount Program agreement beginning January 1, 2025.[2] The participating labeler code list also identifies which labeler codes are eligible for the specified manufacturer or specified small manufacturer phased-in discounts that apply to applicable drugs marketed as of August 16, 2022. The releases that will commence in December 2024 will include both the list of participating labeler codes with the phase-in status of the manufacturer and the more detailed NDC list.

Question: How will CMS identify which applicable drugs of specified manufacturers and specified small manufacturers receive the phase-in discounts?

Answer: Under sections 1860D-14C(g)(4)(B)(i) and 1860D-14C(g)(4)(C)(i) of the Act, respectively, phase-in discounts for specified manufacturers and specified small manufacturers only apply to applicable drugs of such manufacturers that are marketed as of August 16, 2022 (the date of enactment of the IRA). In the Final Guidance, CMS specified that for purposes of identifying applicable drugs of specified manufacturers and specified small manufacturers subject to phase-in discounts, we will determine whether an applicable drug had Part D expenditures on or before

[1] https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf-0

[2] The 2025 participating labeler code list is available in the Downloads section at: https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-information-pharmaceutical-manufacturers.

August 16, 2022, and did not have a marketing end date on the FDA NSDE File before August 17, 2022.

Accordingly, the NDC list will include the following NDC-9s:

1. NDC-9s for applicable drugs for which the associated New Drug Application (NDA) or Biologics License Application (BLA) was approved on or before August 16, 2022 and:

   (a) At least one such NDC-9 had Part D expenditures on or before August 16, 2022; and
   (b) At least one NDC-9 identified in 1(a) did not have a marketing end date on the FDA NSDE File prior to August 17, 2022.

2. NDC-9s for applicable drugs for which the associated NDA or BLA was approved after August 16, 2022 and:

   (a) The product associated with such NDC-9 has the same active moiety or active ingredient and the same holder of the NDA or BLA, respectively, as an NDA or BLA approved on or before August 16, 2022;
   (b) At least one NDC-9 associated with the NDA or BLA in 2(a) that was approved on or before August 16, 2022 had Part D expenditures on or before August 16, 2022; and
   (c) At least one NDC-9 identified in 2(b) did not have a marketing end date on the FDA NSDE File prior to August 17, 2022.

Prior to Prescription Drug Event (PDE) acceptance, the Drug Data Processing System (DDPS) will validate the reported discount on each PDE to ensure that the correct discount is applied to each PDE based on the phase of the benefit, the beneficiary's LIS eligibility, the manufacturer's status as a specified manufacturer or specified small manufacturer, and in accordance with the current published NDC list.

Question: Since phase-in eligibility for a particular applicable drug of a specified manufacturer or specified small manufacturer is based on whether the drug is marketed on one specific, backward-looking date (the date of enactment of the IRA), why is it necessary for CMS to update the NDC list once the initial list is established?

Answer: The identification of NDC-9s subject to phase-in will be an ongoing process as new NDC-9s come to market and existing NDC-9s reach their marketing end dates. In addition, labeler codes and associated NDC-9s that are eligible for phase-ins can change as a result of ownership changes such as the acquisition of one manufacturer by another (see sections 1860D-14C(g)(4)(B)(ii)(III) and 1860D-14C(g)(4)(C)(ii)(III) of the Act).

Question: Should Part D sponsors apply phase-in discounts for new applicable drug NDCs they believe are eligible for phase-in before such NDCs are added to the NDC list?

Answer: No. Because the list will be updated at least monthly, there may be a lag in adding new applicable drug NDCs of specified manufacturers and specified small manufacturers that are eligible for the phase-ins. However, as described above, CMS will not accept PDEs without the correct discount at the time of processing, so the phase-ins cannot be applied unless and until the

NDC is added to the NDC list. Later this year, CMS will provide further instruction related to effective dates when NDCs are added to the list, including any requirements on Part D sponsors to adjust PDEs, as applicable, to reflect the correct discount percentage.

Question: What if a manufacturer identifies what they believe to be an error in the NDC list, such as an NDC-9 of an applicable drug of a specified manufacturer or specified small manufacturer they believe should be added to the list?

Answer: CMS will allow a participating manufacturer that believes that CMS has made an error in the NDC list with respect to any NDC-9 of an applicable drug covered by that manufacturer's Discount Program agreement to submit a request that CMS review the potential error. Participating manufacturers should submit such requests via email to PartDManufacturerDiscountProgram@cms.hhs.gov with the subject line "NDC List Error for [P number]." The request must include a detailed explanation of the purported error, including why the manufacturer believes CMS erred in its assessment of whether a given NDC(s) meets the phase-in criteria, and any supporting documentation. CMS will review and respond to the request within 30 days of receipt, if feasible. Manufacturers may not use this process to raise a dispute about the underlying policies established in the Final Guidance or Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers[3] or applicable drugs of such manufacturers that are eligible for the phase-ins. If CMS determines an error was made, it will correct the error in the next update to the NDC list. CMS also reserves the right to make corrections to the NDC list on its own motion.

CMS encourages specified manufacturers and specified small manufacturers that launch new NDCs under new NDAs or BLAs that they believe meet the phase-in criteria specified in this memorandum to submit information that will facilitate our timely review via email to PartDManufacturerDiscountProgram@cms.hhs.gov. Manufacturers are expected to review the published NDC lists in a timely manner and notify CMS as soon as possible about any errors or omissions with respect to any NDCs of labeler codes covered under their Discount Program agreement. We also remind all participating manufacturers of their obligations under section 80.5 of the Final Guidance and the Discount Program agreement to report changes to corporate ownership, labeler codes, etc. within the required timeframes.

Question: What data sources will CMS use to create and maintain the NDC list?

Answer: CMS will use a variety of data sources to create and maintain the NDC list, including but not limited to the following:

Data Source	Purpose
Drugs@FDA	Used to identify the NDA holder. In the event the BLA holder does not exist in the FDA Purple Book, used to identify the BLA holder
FDA NDC SPL Data Elements (NSDE) File	Used to identify NDCs, marketing category, application numbers, and marketing dates

[3] https://www.cms.gov/files/document/manufacturer-discount-program-specified-and-specified-small-manufacturer-methodology.pdf-0

Data Source	Purpose
FDA Purple Book Database of Licensed Biological Products	Used to identify biological products and BLA holder
FDA SPL Active Ingredient-Active Moiety Relationship/Basis of Strength file	Used as supporting data source to identify active moieties (UNII)
PDE data	Used to identify applicable 9-digit NDCs with Part D expenditures on or before 8/16/2022
RxNorm	Used as supporting data source to identify the active ingredient/active moiety for each NDC

Question: Will the NDC list include NDCs that are not listed with FDA?

Answer: No. Consistent with the requirements in section 80.5.3 of the Final Guidance, the NDC list does not change a manufacturer's obligation to ensure that all labeler codes assigned by the FDA to the manufacturer that contain NDCs for any of the manufacturer's applicable drugs are properly listed on the FDA NDC Directory.[4] CMS does not accept PDEs for NDCs that are not included on the FDA NSDE File. Manufacturers are also expected to maintain up-to-date listings with the electronic database vendors (such as First Databank and Medi-Span) to whom they provide their NDCs for pharmacy claims processing.

Any questions about these FAQs or the Discount Program may be submitted to PartDManufacturerDiscountProgram@cms.hhs.gov.

[4] If a participating manufacturer's Discount Program agreement covers labeler code(s) that are assigned by the FDA to another manufacturer, the participating manufacturer must ensure these requirements are met with respect to such labeler codes.