Medicare Part D Manufacturer Discount Program: Frequently Asked Questions

Last Updated September 6, 2024

CMS will update this list of Frequently Asked Questions (FAQs) as needed to provide information to interested parties. *Updates appear in red, italicized font.*

Question: *Section 80.5.1 of the Medicare Part D Manufacturer Discount Program Final Guidance[1] (Final Guidance) requires manufacturers 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. Is this requirement limited to certain kinds of ownership changes? How should manufacturers provide the notification?*

Answer: *All ownership changes must be reported to CMS. Reporting must be done in a timely manner consistent with the requirements in the Final Guidance and the Discount Program agreement. While this has been a long-standing requirement under the Coverage Gap Discount Program, it is even more important going forward because of the potential impact of such changes on a manufacturer's phase-in eligibility status and the statutory requirement that all members of a controlled group are treated as one manufacturer (see section 50.1 of the Discount Program Final Guidance for more information). At this time, manufacturers should provide the required notifications by email to PartDManufacturerDiscountProgram@cms.hhs.gov. CMS is exploring the feasibility of using the Health Plan Management System (HPMS) for such reporting in the future.*

Question: *How and when should manufacturers submit labeler code changes for January 2025 and beyond?*

Answer: *Manufacturers wishing to add, transfer, or delete labeler codes (as described in section 80.5.2 of the Final Guidance)[2] should continue to use HPMS to request those changes. However, the timeframe for submitting such requests is changing because of the need for additional CMS review related to the Discount Program phase-ins (see section 50.1 of the Final Guidance), including preparation of the NDC list. In order to ensure requested changes are reflected in the January 2025 participating labeler code list and NDC list, manufacturers should submit all requests in HPMS as soon as possible and no later than November 1, 2024. For labeler code changes effective February 2025 or any subsequent month, manufacturers should submit requests in HPMS no later than the first day of the preceding month (e.g., no later than January 1, 2025 to be reflected in the February 2025 labeler code and NDC lists) to ensure the requested change is reflected in the next update. Manufacturers can continue to submit labeler code change requests in HPMS on a rolling basis but should be mindful of the additional time needed to review and process those requests under the Discount Program. CMS may be able to process such requests submitted after the first day of the preceding month depending on volume and agency resources.*

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,

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

[2] *This FAQ refers to labeler code changes that may be submitted in HPMS and does not apply to the removal of labeler codes or NDCs under the circumstances described in section 80.6 of the Final Guidance.*

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 Discount Program 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 *was* released *on May 9,* 2024, and an updated list in *September* 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.[3] 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 *monthly* 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. *The January 2025 participating labeler code and phase-in NDC lists will be released in mid-December 2024. Subsequent lists will be released 5 business days prior to the start of the relevant month and announced through HPMS. The files will be posted on the Part D Information for Pharmaceutical Manufacturers page: https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-information-pharmaceutical-manufacturers.*

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

[3] 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.

Accordingly, the NDC list include*s* 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. *Inclusion of an NDC-9 on the list means that the drug is eligible for phase-in when covered under Part D; it does not constitute a coverage determination or supersede any relevant Medicare or plan coverage criteria.*

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*, or for other NDCs they believe should be on the NDC list but do not appear*? *Likewise, should Part D sponsors not apply phase-in discounts for applicable drug NDCs on the NDC list that they believe are ineligible for phase-in before such NDCs have been removed from the NDC list?*

Answer: No. *A*s 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. *T*he list will be updated monthly, *but* 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 *or populating a Phase-In Eligibility End Date for NDCs that are no longer eligible for the phase-ins*. *If a Part D sponsor identifies what it believes is an error on the NDC list, the sponsor should notify CMS via email to PartDManufacturerDiscountProgram@cms.hhs.gov, and continue to apply phase-in discounts based on the published NDC list. As described below, if CMS determines an error was made, it will be corrected in the next update to the NDC list.*

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[4] or *for identifying* 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:

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

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
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.[5] 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.

Question: *How should Part D sponsors apply discount phase-ins to claims for applicable drugs of specified manufacturers and specified small manufacturers, and do they apply differently to claims for enrollees who are eligible for the low-income subsidy (LIS)?*

Answer: *Under the Discount Program, all Part D enrollees, regardless of LIS status, become applicable beneficiaries once their TrOOP exceeds the statutory Part D deductible. A manufacturer discount is applied to all paid claims involving an applicable drug dispensed to an applicable beneficiary. Generally, the applicable discount is 10% in the initial coverage phase and 20% in the catastrophic phase, unless one of the phase-ins apply. When either phase-in applies, the manufacturer pays a discount of 1% in 2025 (which increases incrementally through the phase-in period ending in 2031) both in the initial coverage phase and the catastrophic phase, as applicable. To facilitate uniform and accurate application of both phase-ins, sponsors must refer to the monthly NDC list published by CMS, which will include all 9-digit NDCs for which either phase-in applies.*

The phased-in discount percentage for specified manufacturers, as described in section 50.1.1 of

[5] 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.

the Final Guidance, is applied to any claim for an applicable drug of a specified manufacturer when (1) the applicable drug is dispensed to an applicable beneficiary who is LIS-eligible on the date of service, and (2) the applicable drug was marketed as of August 16, 2022. Plan sponsors should use the NDC list to identify which NDCs of these manufacturers are eligible for the specified manufacturer phase-in. If the claim is for an NDC of a specified manufacturer and does not appear on the NDC list, this means the drug was not marketed as of August 16, 2022, as determined by CMS, and the phase-in discount percentage does not apply. If the claim is for an NDC of a specified manufacturer and either (1) the applicable beneficiary is not LIS-eligible on the date of service, or (2) the NDC does not appear on the NDC list, the full discount of 10% in the initial coverage phase and 20% in the catastrophic phase is applied.

The phased-in discount percentage for specified small manufacturers, as described in section 50.1.2 of the Final Guidance, is applied to any claim for an applicable drug of a specified small manufacturer when (1) the applicable drug is dispensed to any applicable beneficiary (regardless of LIS status), and (2) the applicable drug was marketed as of August 16, 2022. Again, plan sponsors should use the NDC list released by CMS to identify which NDCs are eligible for the specified small manufacturer phase-in. If the claim is for an NDC of a specified small manufacturer and does not appear on the NDC list, this means the drug was not marketed as of August 16, 2022, as determined by CMS, and the phase-in discount percentage does not apply. If the claim is for an NDC of a specified small manufacturer but the NDC does not appear on the NDC list, the full discount of 10% in the initial coverage phase and 20% in the catastrophic phase is applied.

For more detailed information about the application of manufacturer discounts, including claims involving phase-ins, see the April 15, 2024 HPMS memorandum "Prescription Drug Event Record Reporting Instructions for the Implementation of the Inflation Reduction Act for Contract Year 2025".

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