DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE

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TO: All Programs of All-Inclusive Care for the Elderly (PACE) Organizations

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SUBJECT: PACE Participation in the Manufacturer Discount Program beginning January 1,

2025

This memorandum provides important information for Programs of All-Inclusive Care for the Elderly (PACE) organizations regarding their participation in the Manufacturer Discount Program (Discount Program) beginning on January 1, 2025. Although PACE organizations do not participate in the current Coverage Gap Discount Program (CGDP), they will participate in the Discount Program, as described in previous guidance released by CMS. PACE organizations should prepare for this by carefully reviewing all relevant Heath Plan Management System (HPMS) memoranda and staying apprised of CMS' educational opportunities, as described below.

Background

Section 1860D-14A of the Social Security Act (the Act) made CGDP discounts available to applicable non-low-income Medicare Part D enrollees receiving applicable drugs while in the coverage gap. As required by section 1860D-14A(c)(2) of the Act, CGDP discounts are calculated after the application of supplemental coverage. As such, the CGDP does not apply to PACE organizations because all PACE participants receive either the low-income subsidy for

¹ Note that "Medicare Part D Manufacturer Discount Program Final Guidance," issued November 17, 2023, includes a comment response at page 10 that explicitly states that the Discount program applies to PACE. https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf

prescription drugs or receive supplemental coverage that always brings CGDP discounts down to zero in the coverage gap.

Section 11201(c) of the Inflation Reduction Act of 2022 sunsets the CGDP and establishes the Discount Program, which begins January 1, 2025. As discussed in section 60.2.1 of the Discount Program final guidance, manufacturer discounts under the Discount Program are calculated before supplemental coverage is applied. As a result, there is no statutory basis for excluding PACE organizations from the Discount Program.

Operational Requirements Related to Participation in the Discount Program

Implementation of the Discount Program necessitates significant operational changes for PACE organizations, including reporting an expanded set of data elements on Prescription Drug Event (PDE) submissions and understanding and developing capabilities related to the dispute resolution process for the Discount Program (see section 100 of the Discount Program final guidance). We provide below a brief description of each change and references to recent guidance and instructions released by CMS.

PDE Submissions

PACE participants receive all their Medicare benefits from their PACE organization, including coverage and administration of medically necessary prescription drugs under Part D. PACE organizations administer participants' Part D benefits without limitation or condition as to amount, duration, or scope and without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply to Part D defined standard coverage. Medicare makes prospective payments for Part D, and PACE organizations submit actual cost data through PDE records used to reconcile the prospectively paid amounts.

PACE organizations have historically submitted PDE records with minimum required information. Reconciling each of the Part D payment streams (Low-Income Cost Sharing Subsidy, Direct Subsidy, Reinsurance, and Risk Sharing) has required additional calculation and processing by CMS' Drug Data Processing System (DDPS) for PACE organizations.

Beginning in 2025, PACE organizations will be required to submit a significant amount of additional information on PDE records to support their participation in the Discount Program. CMS has expanded the PDE layout for all Part D plans, effective 2025. CMS will be posting the 2025 layout with specific instructions indicating which PDE fields PACE organizations must submit to effectuate the Discount Program. CMS recommends that PACE organizations review the HPMS memorandum entitled "New 2025 Prescription Drug Event (PDE) File Layouts (FINAL)," released on April 18, 2023, as well as the forthcoming PACE-specific layout instructions.

Manufacturer Discount Program Policy & Operations

PACE organizations will also need to learn about the operational requirements for the Discount Program. Specifically, we encourage PACE organizations to carefully review the HPMS memorandum entitled "Medicare Part D Manufacturer Discount Program Final Guidance," released on November 17, 2023, and to become familiar with the dispute resolution processes described in section 100. Additional operational guidance on the Discount Program will be

forthcoming on topics such as establishing connectivity with the Discount Program Third Party Administrator for receipt of invoicing reports, checking reports through our data integrity contractor, and processing manufacturers' disputes and appeals.

Resources

CMS intends to conduct several technical assistance and training sessions to help PACE organizations prepare for these changes. Details regarding these trainings will be announced in upcoming HPMS memoranda.

Helpful Links

Medicare Part D Manufacturer Discount Program Final Guidance (November 17, 2023) New 2025 Prescription Drug Event (PDE) File Layouts (FINAL) (April 18, 2023)

Resource Mailboxes

General questions about the Discount Program can be sent to PartDManufacturerDiscountProgram@cms.hhs.gov

Questions about PDE guidance can be submitted to PDE-Operations@cms.hhs.gov