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**DATE:** October 20, 2026

**TO:** Part D Sponsors

**FROM:** Vanessa S. Duran, Director  
Medicare Drug Benefit and C&D Data Group

**SUBJECT:** Draft Program Instructions for Identifying Essential Pharmacies and Affiliated Retail Pharmacy Data Collection: Section 6223(b) of the Consolidated Appropriations Act, 2026 – 30-Day Comment Period

Section 6223(b) of the Consolidated Appropriations Act, 2026 (Pub. L. 119-75) (CAA, 2026) establishes new requirements in section 1860D-42(e) of the Social Security Act (the Act) for identifying and publishing an annual list of essential retail pharmacies (EPs)<sup>1</sup> and preparing biennial informational reports comparing EPs to pharmacies that are not EPs on various data points.

Pursuant to section 1860D-42(e)(3)(A) of the Act, CMS is required to publish a list of EPs on a publicly accessible CMS website for each plan year beginning with plan year 2028. To support this effort, section 1860D-42(e)(3)(B) of the Act requires all Prescription Drug Plan (PDP) sponsors offering prescription drug plans and Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug (MA-PD) plans (collectively referred to as Part D sponsors) to submit to CMS lists of their affiliated retail pharmacies (APs) for each plan year beginning with plan year 2028. CMS will rely on these AP submissions to identify EPs, which by definition are pharmacies that are not affiliated with a Part D sponsor or a pharmacy benefit manager (PBM).

CMS is issuing these Draft Program Instructions for Identifying Essential Pharmacies and Affiliated Retail Pharmacy Data Collection pursuant to CMS's statutory authority under section 1860D-42(e)(3)(D) of the Act, which provides that the Secretary may implement this paragraph "by program instruction or otherwise," and is soliciting comments from Part D sponsors and interested parties. CMS invites stakeholders to send comments to [PartDEssentialPharmacy@cms.hhs.gov](mailto:PartDEssentialPharmacy@cms.hhs.gov) with the subject line "Draft Program Instructions – Affiliated Retail Pharmacy Data Collection." CMS will consider comments received **by 11:59 PM Eastern Time on November 19, 2026.**

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<sup>1</sup> As defined in section 1860D-42(e)(2) of the Act.

CMS will issue Final Program Instructions after considering the public comments received in response to these Draft Program Instructions. The Final Program Instructions will be issued following the conclusion of notice-and-comment rulemaking implementing section 6224 of the CAA, 2026,<sup>2</sup> including the definitions for the terms “affiliate” and “pharmacy benefit manager.” Section 1860D-42(e)(4) of the Act states that for the purposes of section 1860D-42(e) of the Act, such terms shall have the meaning given those terms in section 1860D-12(h)(7) of the Act, as added by section 6224 of the CAA, 2026.

In the Final Program Instructions, CMS may change any policies, including policies on which CMS has not expressly solicited comment, based on the agency's further consideration of the relevant issues. Policies established in the Final Program Instructions are subject to change in subsequent years, including to account for regulatory developments prior to the date of the required submission.

If any provision of these Program Instructions, once finalized, is held to be invalid or unenforceable, CMS intends that it shall be severable from the remainder of these Program Instructions, and shall not affect the remainder thereof, or the application of the provision to other persons or circumstances. CMS has determined that all relevant provisions of the guidance could function independently from one another.

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<sup>2</sup> Consolidated Appropriations Act, 2026, Section 6224 amends the Social Security Act by establishing requirements related to pharmacy benefit managers (PBMs) and their affiliates specific to the Medicare Part D program. For proposed regulations implementing Section 6224 of the CAA, 2026, please see Medicare Program; Contract Year 2028 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Programs of All-Inclusive Care for the Elderly CMS-4214-P (91 FR 66408) available at <https://www.federalregister.gov/d/2026-21420>.

# **Draft Identifying Essential Pharmacies and Affiliated Retail Pharmacy Data Collection Program Instructions**

## Table of Contents

|                                                            |    |
|------------------------------------------------------------|----|
| 1. Introduction.....                                       | 4  |
| 2. Definitions.....                                        | 4  |
| 3. Affiliated Retail Pharmacy Reporting Requirements ..... | 6  |
| 3.1 Purpose.....                                           | 6  |
| 3.2 Use of Part D Pricing File Submission .....            | 6  |
| 3.3 Organization Types Required to Report .....            | 6  |
| 3.4 Geographic Scope .....                                 | 7  |
| 3.5 Required AP Data Reporting Elements .....              | 7  |
| 3.6 Submission Frequency .....                             | 7  |
| 3.7 Data Submission Process .....                          | 8  |
| 3.8 Data Quality and Accuracy .....                        | 8  |
| 4. Data Use.....                                           | 8  |
| 5. Appendix A: Key Statutory References.....               | 9  |
| 6. Appendix B: Additional Key Definitions .....            | 10 |

## 1. Introduction

Section 6223(b) of the Consolidated Appropriations Act of 2026 (Pub. L. 119-75) (CAA, 2026) establishes new requirements in section 1860D-42(e) of the Social Security Act (the Act) for identifying and publishing an annual list of essential retail pharmacies (EPs) and preparing biennial informational reports comparing EPs to pharmacies that are not EPs on various data points.<sup>3</sup>

Pursuant to section 1860D-42(e)(3)(A) of the Act, CMS is required to publish a list of EPs on a publicly accessible CMS website for each plan year beginning with plan year 2028. Section 1860D-42(e)(3)(B) of the Act requires that each sponsor offering Prescription Drug Plans (PDPs) and Medicare Advantage (MA) organizations offering Medicare Advantage Prescription Drug (MA-PD) plans (collectively referred to as Part D sponsors) submit a list of retail pharmacies that are affiliates of the sponsor or organization, or are affiliates of a pharmacy benefit manager (PBM) acting on behalf of such sponsor or organization, for each plan year beginning with plan year 2028. We refer to these pharmacies as affiliated retail pharmacies (APs) in this document.

In accordance with our authority under section 1860D-42(e)(3)(D) of the Act, CMS is issuing these Draft Program Instructions to describe CMS's approach to identifying EPs and provide guidance to Part D sponsors on reporting AP information to CMS, as required by section 1860D-42(e)(3) of the Act.

## 2. Definitions

“Affiliate” (defined in section 1860D-12(h)(7)(A) of the Act) means, with respect to any pharmacy benefit manager or Part D sponsor, any entity that, directly or indirectly:

- Owns or is owned by, controls or is controlled by, or is otherwise related in any ownership structure to such PBM or Part D sponsor; or
- Acts as a contractor, principal, or agent to such PBM or Part D sponsor, insofar as such contractor, principal, or agent performs any of the functions performed by a PBM as defined under section 1860D-12(h)(7)(C) of the Act.

“Pharmacy Benefit Manager” (defined in section 1860D-12(h)(7)(C) of the Act) means any person or entity that, either directly or through an intermediary, acts as a price negotiator or group purchaser on behalf of a PDP sponsor or prescription drug plan, or manages the prescription drug benefits provided by such sponsor or plan, including:

- The processing and payment of claims for prescription drugs,
- The performance of drug utilization review,
- The processing of drug prior authorization requests,

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<sup>3</sup> These Draft Program Instructions do not address section 1860D-42(e)(3)(C) of the Act, which requires Part D sponsors to submit information on incentive payments and other fees paid by such sponsor to pharmacies, insofar as any such payments or fees are not otherwise reported. CMS will issue additional program instructions to Part D sponsors on this reporting at a later date.

- The adjudication of appeals or grievances related to the prescription drug benefit,
- Contracting with network pharmacies,
- Controlling the cost of covered part D drugs, or
- The provision of related services.

Such term includes any person or entity that carries out one or more of the activities described above, irrespective of whether such person or entity calls itself a “pharmacy benefit manager”.

Section 1860D-42(e)(4) of the Act states that for the purposes of section 1860D-42(e) of the Act, the terms “affiliate” and “pharmacy benefit manager” shall have the meaning given those terms in section 1860D-12(h)(7) of the Act.

CMS is soliciting comment on proposed regulatory definitions of “affiliate” and “pharmacy benefit manager” for the purposes of implementing section 1860D-12(h)(7) of the Act as part of the notice of proposed rulemaking Medicare Program; Contract Year 2028 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Programs of All-Inclusive Care for the Elderly “CMS-4214-P” (91 FR 66408).<sup>4</sup> The comment period ends on December 15, 2026.

“Essential retail pharmacy” is defined in section 1860D-42(e)(2) of the Act as, with respect to a plan year, a retail pharmacy that is not an affiliate as defined above, which we refer to as a non-affiliated retail pharmacy (non-AP) in this document, that meets the following geographic proximity criteria – i.e., there is no other retail pharmacy within the specified distance:

Table 1. Distance Thresholds for Identifying Essential Pharmacies in Rural, Suburban and Urban Areas

| <b>Geographic Area Type</b> | <b>Distance Threshold</b>                                                |
|-----------------------------|--------------------------------------------------------------------------|
| Rural                       | No other retail pharmacy within 10 miles, as determined by the Secretary |
| Suburban                    | No other retail pharmacy within 2 miles, as determined by the Secretary  |
| Urban                       | No other retail pharmacy within 1 mile, as determined by the Secretary   |

CMS will establish a methodology for assessing the distance thresholds used to identify EPs. When evaluating convenient access to retail pharmacies under 42 CFR § 423.120(a)(1), CMS currently employs a Euclidean distance methodology, which calculates the straight-line distance between two points, specifically, the centroid of beneficiaries’ ZIP Codes, used as a proxy for the beneficiaries’ location, and the location of the nearest network retail pharmacy. The Euclidean distance approach to assess distance thresholds between retail pharmacies to identify EPs is consistent with the existing pharmacy access methodology and relatively simple to calculate. Using driving distance to assess distance thresholds between retail pharmacies to identify EPs, by contrast, would provide a more accurate representation of the actual travel burden

<sup>4</sup> Please see: <https://www.federalregister.gov/d/2026-21420>.

experienced by beneficiaries. Accordingly, CMS is evaluating driving mileage as a potential methodology for assessing the distance thresholds used to identify EPs.

We solicit public comment on the methodology for assessing distance thresholds used to identify EPs, including a measurement approach based on driving distance as well as data sources and calculation methods CMS could use for implementation of section 1860D-42(e) of the Act. We note that the distance thresholds specified in Table 1 are established by statute and are not subject to modification by CMS. We therefore solicit comment only on methodologies CMS could use to measure whether those statutory distance thresholds are met. CMS will finalize the methodology for calculating distance under section 1860D-42(e) of the Act in the Final Program Instructions.

### 3. Affiliated Retail Pharmacy Reporting Requirements

#### 3.1 Purpose

The accurate identification and publication of EPs depend on CMS's ability to distinguish APs from non-affiliated retail pharmacies. Section 1860D-42(e)(3)(B) of the Act requires that each Part D sponsor submit a list of retail pharmacies that are affiliates of the sponsor or are affiliates of a PBM acting on behalf of such sponsor for each plan year. Therefore, CMS is establishing the Affiliated Retail Pharmacy Data Collection for Part D sponsors to report necessary information (referred to in this document as AP Data, as defined in Appendix B) for CMS to develop a list of EPs.

#### 3.2 Use of Part D Pricing File Submission

For each plan year, CMS will develop the EP list using retail pharmacy network data submitted by Part D sponsors through the Pharmacy Cost (PC) file in the Part D Pricing File Submission (PDPFS) module of the Health Plan Management System (HPMS). These data are also used for display in Medicare Plan Finder (MPF). The EP list will be developed based on data submitted for the first Annual Enrollment Period (AEP) posting on MPF in October 2027. This approach leverages an existing data collection and minimizes additional reporting burden for Part D sponsors.

Consistent with the definition in section 1860D-42(e)(2) of the Act, any retail pharmacy identified as an AP by any Part D sponsor in its PDPFS submission during the window used for the first AEP posting on MPF in October of each year will be excluded from the EP list for that plan year, even if the pharmacy otherwise satisfies the geographic proximity criteria.

#### 3.3 Organization Types Required to Report

Part D sponsors that submit their drug pricing and pharmacy data in HPMS for posting on MPF will be required to submit AP Data annually. The following Part D sponsor types do not currently submit drug pricing and pharmacy data files for MPF and therefore will not be required to submit AP Data:

- Employer Group Waiver-only Plans and Employer-Direct (EGWPs),
- Health Care Prepayment Plan under Section 1833 of the Social Security Act (HCPP-1833 Cost),
- National Program of All-Inclusive Care for the Elderly (PACE), and
- Medicare Limited Income Newly Eligible Transition Program (LI NET).

### 3.4 Geographic Scope

The AP Data collection requirements will apply only with respect to retail pharmacies located in the 50 states and the District of Columbia.

### 3.5 Required AP Data Reporting Elements

CMS will use the National Provider Identifier (NPI) as the primary identifier for retail pharmacies included on the EP list. Beginning with plan year 2028, Part D sponsors must submit the following data elements for each AP at the contract-plan-segment level.

Table 2. File Layout for Submission of Affiliated Pharmacies

| <b>Data Element</b>                     | <b>Data Element Description</b>                                                                                                               |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Contract ID</b>                      | Organization's contract number that is assigned by CMS.<br>Example: H9999                                                                     |
| <b>Plan ID</b>                          | Plan ID assigned by CMS that is associated with this AP file. Include leading zeros. Example: 001                                             |
| <b>Segment ID</b>                       | Segment ID associated with the plan ID. Include leading zeros. Example: 001. Note: If the plan is not segmented, use 000 for this field.      |
| <b>Pharmacy Number</b>                  | This is the 12-digit pharmacy number, which is the 10-digit NPI number with leading one and zero.                                             |
| <b>Affiliation</b>                      | 1 = Affiliated with Part D Sponsor<br>2 = Affiliated with PBM<br>3 = Affiliated with Both                                                     |
| <b>Name of Affiliate Part D sponsor</b> | Enter the name of the Part D sponsor if the pharmacy is affiliated with the sponsor. Otherwise leave blank. Required if Affiliation = 1 or 3. |
| <b>Name of Affiliate PBM</b>            | Enter the name of the PBM if the pharmacy is affiliated with the PBM. Otherwise leave blank. Required if Affiliation = 2 or 3.                |

### 3.6 Submission Frequency

Part D sponsors will submit the required data elements for all APs on an annual basis prior to the start of each contract year (CY). Part D sponsors will align their AP Data to the retail pharmacy network data that is submitted through the PC file in the PDPFS module during the submission window used for the first AEP posting on MPF in October prior to the next CY. For example,

Part D sponsors will submit their CY 2028 AP Data based on their PC files submitted for the first AEP posting on MPF in October 2027.

CMS will publish submission deadlines annually after the initial collection for CY 2028.

### 3.7 Data Submission Process

All AP Data must be submitted through the HPMS Network Management Module (NMM), accessible at <https://hpms.cms.gov>. CMS will provide detailed screen shots and supplemental submission guidance in the Final Program Instructions.

### 3.8 Data Quality and Accuracy

Sponsors are responsible for the completeness and accuracy of all submitted data. CMS will review submissions for completeness of required data elements, consistency with other data sources available to CMS, and for accuracy of AP designations.

## 4. Data Use

CMS will use data submitted pursuant to the Final Program Instructions to identify and publish the annual list of EPs and prepare the biennial public reports required under section 1860D–42(e) of the Act. CMS will first publish the list of EPs on CMS.gov in summer 2028 and annually thereafter. The list of EPs will include pharmacy name, address, NPI, and geography type (rural/urban/suburban). CMS will issue an HPMS memo notifying Part D sponsors and stakeholders of the annual publication.

This data collection is for informational purposes only and will not be used to determine compliance with other Part D program requirements. However, Part D sponsors must submit timely, complete, and accurate AP Data that are aligned to the retail pharmacy network data submitted in the PDPFS module. Non-compliance with the data submission requirements may result in compliance actions under 42 CFR Part 423.

## 5. Appendix A: Key Statutory References

| Provision                                                                                                     | Citation                                    |
|---------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Essential retail pharmacy definition, CMS publication requirements, and Part D sponsor reporting requirements | Section 1860D–42(e), Social Security Act    |
| Definition of “affiliate” and “pharmacy benefit manager”                                                      | Section 1860D–12(h)(7), Social Security Act |
| Part D regulations                                                                                            | 42 CFR Part 423                             |

## 6. Appendix B: Additional Key Definitions

**AP Data:** The required data elements described in Section 3.5 of these Draft Program Instructions that a Part D sponsor must submit for each AP, including pharmacies affiliated with a PBM acting on behalf of the sponsor, at the contract-plan-segment level, pursuant to section 1860D–42(e)(3)(B) of the Social Security Act.

**Health Plan Management System (HPMS):** A CMS web-enabled information system that supports the ongoing operations of the Medicare Advantage (MA) and Prescription Drug (Part D) programs, including data collection and reporting, program operations, oversight, compliance, and analysis.

**Network Management Module (NMM):** The HPMS module responsible for collecting and processing plan network submissions.

**Pharmacy Cost (PC) File:** The PC file is used as part of Part D Pricing File Submission (PDPFS) to identify the pharmacies participating in each Part D plan's network and specify their attributes, including preferred/standard status, retail or mail-order designation, and applicable dispensing fees. CMS uses this information to support drug-cost calculations and pharmacy displays in Medicare Plan Finder.

**Retail Pharmacy:** Any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy (42 CFR § 423.100).