and replace the date ''January 8, 2018'' with ''December 13, 2022''.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2026–19579 Filed 9–23–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS–4217–NC]

RIN 0938–AW08

Request for Information; Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: This request for information (RFI) solicits input from interested parties for purposes of establishing standards for reasonable and relevant pharmacy contract terms and conditions under the Medicare prescription drug benefit. Section 6223(a) of the Consolidated Appropriations Act, 2026 (CAA, 2026) amends section 1860D–4(b)(1)(A) of the Social Security Act (the Act) to require Part D plan sponsors to permit any pharmacy that meets standard contract terms and conditions under the plan to participate as a network pharmacy of the plan. Section 6223(a) of the CAA, 2026 further requires that, notwithstanding any other provision of law, for plan years beginning January 1, 2029, such standard contract terms and conditions offered by Part D plan sponsors must be reasonable and relevant according to standards established by the Secretary of the Department of Health and Human Services. Finally, section 6223(a) of the CAA, 2026 requires the Secretary to issue this RFI for purposes of establishing such standards.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by November 23, 2026.

ADDRESSES: In commenting, refer to file code CMS–4217–NC.

Comments, including mass comment submissions, must be submitted in *one* of the following three ways (please choose only *one* of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov/docket/CMS-2026-3037.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4217–NC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4217–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Beckie Peyton, (410) 786–1572. *PartDPolicy@cms.hhs.gov,* for general questions related to section 6223 of the CAA, 2026 (''Assuring Pharmacy Access and Choice for Medicare Beneficiaries'').

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended Title XVIII of the Act by establishing a new Part D: the Voluntary Prescription Drug Benefit Program. In general, private companies—referred to as Part D plan sponsors—contract with CMS to provide the Part D benefit either through standalone prescription drug plans (PDPs) that offer prescription drug coverage only, or through Medicare Advantage plans that offer integrated prescription drug and health care coverage (MA–PD plans). Part D plan sponsors must establish contracted pharmacy networks that meet the Part D convenient access standards specified in 42 CFR 423.120(a). In establishing these contracted pharmacy networks, Part D plan sponsors must contract with any pharmacy that meets the Part D plan sponsor's standard terms and conditions (see § 423.120(a)(8)(i)). Such standard terms and conditions must be reasonable and relevant (see § 423.505(b)(18)). In the January 28, 2005 Part D final rule (70 FR 4254), we clarified that standard terms and conditions, particularly for payment terms, may vary to accommodate geographic areas or types of pharmacies, and that modifying such terms and conditions would be acceptable provided that all similarly situated pharmacies are offered the same standard terms and conditions. CMS has not established additional requirements for what constitutes reasonable and relevant terms and conditions. Section 6223(a) of the CAA, 2026 amends section 1860D–4(b)(1)(A) of the Act to require Part D plan sponsors offering a prescription drug plan to permit any pharmacy that meets the standard contract terms and conditions of such plan to participate as a network pharmacy of the plan. Section 6223(a) of the CAA, 2026 adds new clause (ii) to section 1860D–4(b)(1)(A) that requires the Secretary of the Department of Health and Human Services (the Secretary) to establish standards for reasonable and relevant contract terms and conditions no later than the first Monday in April of 2028, for plan years beginning on or after January 1, 2029.

Under new section 1860D–4(b)(1)(A)(ii)(III) of the Act, the Secretary is required to issue an RFI not later than April 1, 2027 for purposes of establishing the standards for reasonable and relevant contract terms and conditions and to seek input on specific topics. Accordingly, CMS is issuing this RFI to inform future rulemaking and in section II. of this RFI seeks input on the specific topics required under section 1860D–4(b)(1)(A)(ii)(III) of the Act.

II. Solicitation of Public Comments

Consistent with the requirements of section 1860D–4(b)(1)(A)(ii)(III) of the Act, CMS is seeking information from interested parties regarding the topics described below, for purposes of establishing standards as required under

section 1860D–4(b)(1)(A)(ii)(II) of the Act.

In preparing submissions, respondents should clearly identify which section(s) of this RFI they are responding to and the circumstances to which their responses relate. Commenters may wish to consider any of the following factors, and indicate within their submissions the relevance of these or other factors:

- Subsets of pharmacies or pharmacy services (for example, retail; mail order; home infusion; long-term care (LTC); specialty; compounding; Indian Health Service, Tribal, and Urban Indian (I/T/U));
- Non-preferred versus preferred network arrangements;
- Geographic location of the pharmacy (for example, rural, urban);
- Drug type (for example, brand name, generic, high-cost, specialty, special handling, limited distribution, compounded products);
- Plan type (for example, PDP, MA–PD); and
- Vertical integration, that is, the control within a single corporate structure of various roles in the prescription drug supply chain, including insurance plans, pharmacy benefit managers (PBMs), and pharmacies. In addition to the topics discussed in each of the sections below, we solicit comment on how implementation of standards for reasonable and relevant pharmacy contract provisions in section 1860D–4(b)(1)(A)(ii)(II) of the Act is likely to overlap with implementation of the PBM disclosure requirements and remuneration restrictions set forth under section 1860D–12(h) of the Act, and recommendations for how CMS should take such overlap into account when developing the standards for reasonable and relevant pharmacy contract provisions.

Commenters are encouraged to provide as much detail as possible in their submissions. In preparing responses, CMS encourages commenters to provide, where relevant, quantitative data and empirical analyses; contract language (de-identified as appropriate); information disaggregated by pharmacy type, geographic location, drug category, or other relevant factors; and evidence regarding Part D enrollee access and outcomes.[1]

A. Pharmacy Reimbursement and Dispensing Fees

CMS seeks information about whether pharmacy reimbursement and dispensing fees paid by Part D sponsors to network pharmacies sufficiently cover the ingredient and operational costs of such pharmacies. Specific areas of interest include:

- Information about Part D pharmacy reimbursement policies, including variations by pharmacy type, geographic location, drug type (for example, generic, brand, specialty), or other factors;
- How Part D reimbursement rates compare to pharmacy actual acquisition costs, which methodologies and pricing benchmarks most closely reflect actual acquisition costs, and whether rates vary for certain drugs or drug types, pharmacy types, or other factors;
- The feasibility and utility of network pharmacies sharing their actual acquisition costs with Part D plan sponsors, either directly or via wholesalers, and whether that transparency would be a sufficient alternative to benchmarks or similar methodologies to establish a reasonable cost-based reimbursement methodology for ingredient costs;
- Whether, and how, pharmacy margins on ingredient costs differ for certain drugs or drug classes (for example, brand-name drugs versus generics);
- Whether, and how, reimbursement policies impact pharmacy decisions to stock certain drugs or drug classes (for example, high-cost drugs);
- The frequency of plan updates to maximum allowable cost (MAC) pricing lists, communication regarding such updates, and related dispute resolution mechanisms;
- Industry standards or common practices for establishing MAC prices and whether there are alternatives that are more transparent to pharmacies;
- The use of ''lesser of'' pricing methodologies, including the use of usual and customary (U&C) pricing and how U&C is defined;
- The use of machine learning to estimate acquisition costs;
- Opportunities for the use of artificial intelligence (AI) with respect to Part D pharmacy reimbursement;
- Information on standard Part D pharmacy contract terms and conditions relating to dispensing covered Part D drugs to 340B patients enrolled in Part D, including whether such 340B specific terms and conditions are common, and whether and how Part D plan sponsors determine when a claim is for a 340B patient for which the pharmacy acquisition cost is less than the plan's negotiated price;
- The relationship, if any, between Part D reimbursement rates and the presence of ''pharmacy deserts'' in rural, urban, or other underserved areas;
- Costs that are considered within the scope of dispensing fees, and whether dispensing fees paid by Part D sponsors sufficiently cover those costs;
- How dispensing fees are determined in Part D and outside of Part D;
- Whether dispensing fees should be required to cover the cost of dispensing irrespective of the ingredient cost reimbursement or whether reimbursement of the ingredient cost may be factored into the dispensing fee calculation;
- Whether and how dispensing fees vary by pharmacy type, pharmacy services, or other factors;
- Impacts of post-adjudication adjustments on net reimbursement rates;
- The extent to which negotiated prices reported on pharmacy claim responses reflect a pharmacy's final reimbursement for Part D claims versus an aggregate guarantee such as a generic effective rate (GER), brand effective rate (BER), or similar reimbursement methodologies reconciled after the point of sale; the magnitude of the difference between negotiated prices reported on pharmacy claim responses and end-of-year reconciled effective rates; and whether claim-level reimbursement is meaningfully predictive of the amount the pharmacy actually receives over the contract year.
- The extent to which the use of aggregate guarantee reimbursement methodologies, or the parameters of such methodologies, are negotiable between pharmacies and Part D sponsors.
- The extent to which aggregate guarantee reimbursement methodologies influence decisions by pharmacies about drug selection, particularly in the case of high-cost specialty generics;
- The extent to which a pharmacy's Part D reimbursement rates are set or adjusted in relation to the same pharmacy's commercial reimbursement rates, including:

++ Whether any guarantee covers both Part D and commercial reimbursement;

++ Whether and how MAC prices, dispensing fees, or other reimbursement parameters are managed so that overpayments relative to the guarantee on one line of business offset underpayments on the other;

++ Whether such arrangements could result in higher Part D negotiated prices

[1] Commenters should not include proprietary or confidential information in their submissions. We note that as independent regulatory obligations, Part D sponsors and their first tier, downstream, and related entities must make available documentation as the Secretary deems necessary to enforce CMS' contract with the Part D sponsor, including documents with the terms and conditions offered by Part D sponsors to pharmacies. See 42 CFR 423.505(e)(2) and (i)(2).

than would be paid under a standalone Part D guarantee, and what the implications for CMS subsidy calculations, enrollee cost sharing, and Part D bids would be;

++ The prevalence of contract provisions that tie Part D reimbursement rates to commercial reimbursement rates, and any variances across pharmacy types.

++ The frequency and magnitude of end-of-year reconciliation payments arising from aggregate guarantee constructs, and whether such reconciliation payments are allocated differently across Part D and commercial lines of business and, if so, how;

- The predictability of final reimbursement at the time of dispensing;
- Whether the remittance advice provided to network pharmacies include sufficient claim level detail for the pharmacy to determine how much it was reimbursed for each claim, including after point-of-sale adjustments; and
- Whether CMS should establish reimbursement methodologies or rates as part of the standards for reasonable and relevant pharmacy contract terms and conditions.

B. Current Contracting Practices

CMS seeks information regarding current Part D plan and network pharmacy contracting practices. Specific areas of interest include:

- The factors CMS should consider in determining the reasonableness and relevance of contract terms and conditions between prescription drug plans and network pharmacies, including whether such terms and conditions facilitate or hinder competition, promote enrollee access to Part D drugs, and align with evidence-based quality metrics;
- With respect to the current requirements at § 423.505(b)(18), how Part D plan sponsors differentiate among the contract terms and conditions made available to pharmacies based on whether the pharmacies are ''similarly situated'' to other pharmacies, what criteria sponsors use to determine that individual pharmacies are similarly situated, and how sponsors ensure consistent application of those criteria;
- Whether Part D plan sponsors offer any willing pharmacy terms and conditions to participate in their non-preferred networks only, or if such terms and conditions are also offered to any willing pharmacy for participation in preferred networks;
- Whether pharmacies meeting the same objective criteria (for example, accreditation, dispensing capability, clinical services) are offered the opportunity to participate as specialty network pharmacies under the same terms and conditions, and how ''similarly situated'' is determined for specialty pharmacy purposes;
- The extent to which limited or exclusive specialty networks, manufacturer limited-distribution designations, and PBM specialty pharmacy designations overlap with, or are influenced by, common ownership between the PBM and the designated specialty pharmacy;
- The relationship between specialty pharmacy or specialty drug designation and reimbursement terms, including whether such designation results in materially different ingredient cost reimbursement, dispensing fees, performance measures, or audit treatment;
- Whether CMS should establish standards related to the definition of ''specialty pharmacy'' in the context of Part D pharmacy contracting, including any standards for the criteria a network pharmacy must meet to be eligible for specialty designation.
- The extent to which a pharmacy's participation in a Part D plan sponsor's non-Part D pharmacy network impacts its ability to participate in the plan sponsor's Part D network, the terms of its contract for participation in the plan sponsor's Part D network, or both;
- Whether current Part D pharmacy contracting practices differ from non-Part D pharmacy contracting practices and, if so, information about such differences;
- Whether standard Part D pharmacy contract terms and conditions are offered as standalone Part D contracts or as part of a broader network agreement covering multiple lines of business (for example, Medicaid managed care, commercial, exchange), and whether the multi-line structure affects the terms applicable to Part D specifically;
- Whether Part D plan sponsors have policies related to so-called ''brown bagging'' or ''white bagging'', how those terms are understood by the parties, and their effect on the contracting process;
- The use of provider manuals, policy bulletins, or other Part D plan sponsor or PBM communications to modify or supplement standard contract terms and conditions outside of formal contract amendment;
- The extent to which the financial terms that ultimately determine pharmacy reimbursement are contained in documents other than the executed contract (for example, rate sheets, internal budget files, side letters, or unwritten understandings between affiliated entities), and whether and how transparency about such documents could be improved;
- The role and impact of PBMs, pharmacy services administrative organizations (PSAOs), and other entities on the Part D pharmacy contracting process;
- The relative leverage Part D plan sponsors, PBMs, and pharmacies have in negotiations over contract terms and conditions and network participation; the variation of such leverage by pharmacy type, geographic location, or other factors; and the extent to which CMS rules and guidance affect, or could affect, this balance;
- With respect to pharmacy contract provisions that permit Part D plan sponsors to recoup or suspend pharmacy payment or terminate a pharmacy contract:

++ The prevalence of such provisions;

++ The conditions necessary to invoke such provisions, such as a credible allegation of fraud or other inappropriate billing or risk of patient harm;

++ Whether such provisions include an appeal process and, if so, the extent to which such appeal process is utilized and the outcomes of such appeals.

- With respect to acceptance of standard Part D pharmacy contract terms and conditions:

++ The amount of time pharmacies (and their PSAOs) are given to review proposed standard terms and conditions, rate sheets, and amendments before acceptance is required or deemed;

++ The use of deemed acceptance or negative-consent provisions (for example, terms treated as accepted if the pharmacy does not respond within a certain timeframe);

++ Whether pharmacies receive complete reimbursement information—including ingredient cost methodology, dispensing fees, applicable effective-rate guarantees, performance measures, and direct and indirect remuneration (DIR) fee structures—at the time the contract or amendment is offered;

++ Whether the timing and completeness of disclosures are sufficient to constitute a reasonable opportunity to evaluate and accept terms within the meaning of section 1860D–4(b)(1)(A) of the Act;

- How often standard terms and conditions, MAC lists, or other reimbursement parameters are modified mid-contract; the notice provided to network pharmacies before such modifications take effect; who has authority to make such changes; and

whether pharmacies have a meaningful opportunity to decline modified terms without losing network participation;

- Whether CMS should establish minimum review periods, disclosure requirements, or affirmative acceptance requirements (as opposed to deemed acceptance) for standard contract terms, amendments, and material reimbursement changes as part of the standards for reasonable and relevant pharmacy contract terms and conditions;
- With respect to pharmacy contract terms and conditions, whether related to pharmacy reimbursement or otherwise:

++ Whether a mechanism is provided to resolve disputes about such terms, and the adequacy of such mechanisms;

++ What limitations, if any, are placed on a pharmacy's ability to file disputes;

++ Whether dispute resolution procedures are clearly outlined;

++ How disputes are adjudicated, and by whom;

++ Resolution timeframes; and

++ Approval and denial rates;

- Incentives, if any, that help foster a level playing field between the parties; and
- Other ways to ensure transparency and fairness in Part D pharmacy contracting.

C. Trends in Contract Terms and Conditions

CMS seeks information regarding trends in Part D plan sponsor and network pharmacy contract terms and conditions. Specific areas of interest include—

- Reimbursement methodologies for dispensing services, including but not limited to the use of MAC pricing and other pricing benchmarks relied on for ingredient costs and incentive payments;
- Payment methodologies for other payments made to network pharmacies by Part D plan sponsors or PBMs, and any payments from network pharmacies to Part D plan sponsors or PBMs (for example, network participation fees);
- Performance-based pharmacy payment models;
- The uniformity of terms and conditions offered by different Part D plan sponsors and plan types;
- Terms and conditions offered to pharmacies with multiple lines of business (for example, retail, LTC, specialty), and how such terms and conditions accommodate the multiple lines of business;
- Terms and conditions for non-dispensing services (including information about what the non-dispensing services are and how they are compensated), and whether non-dispensing services generally are included in or negotiated outside of the standard contract terms and conditions referred to in section 1860D–4(b)(1)(A)(i) of the Act;
- The complexity of Part D pharmacy contracting terms and conditions and issues related to transparency;
- Impacts of the Inflation Reduction Act of 2022 on Part D pharmacy contracting, including the impact of maximum fair prices (MFPs) under the Medicare Drug Price Negotiation Program on Part D pharmacy reimbursement terms for both selected drugs and non-selected drugs; and
- Trends related to the use of guarantees that utilize a single effective rate target for both Part D and commercial lines of business.

D. Pharmacy Quality and Performance Measures

CMS seeks information about the use and application of pharmacy quality measures (or other measures used to evaluate pharmacy performance) by Part D plan sponsors for network pharmacies. Specific areas of interest include—

- How such measures are incorporated into network pharmacy contracts;
- What measures are used, including methodology and measure steward;
- Whether measures are applied uniformly across pharmacies, or how specifications vary by pharmacy type or other pharmacy attributes;
- How such measures are used to monitor pharmacy performance, including success/failure performance threshold(s), or impact to pharmacy reimbursement or preferred network placement;
- Whether and how measures are validated or risk-adjusted;
- How performance impacts enrollee outcomes or the financial implications for Part D plan sponsors and pharmacies;
- Whether and how often network pharmacies receive access to performance measure data;
- Whether any measures are aligned with CMS' contract-level Part D Star Ratings measures, and how any measures have been re-specified at the pharmacy level;
- Information about disproportionate impacts of pharmacy quality or performance measures on particular pharmacy types or pharmacy characteristics (for example, pharmacy size, setting, and non-chain type); and
- Appeal processes for pharmacies regarding their performance measures.

E. Auditing Practices

CMS seeks information regarding Part D plan sponsor auditing practices for network pharmacies. Areas of interest include—

- The frequency and type of pharmacy audits conducted;
- Transparency of audit and recoupment methodologies, including whether pharmacies are provided with information on a per claim basis;
- Information about common audit findings and financial and other impacts on pharmacies and plans;
- The extent to which pharmacy audits are used for or result in identification of administrative or clerical issues versus issues related to patient care or program integrity vulnerabilities such as fraud or other improper billing;
- Extrapolation methods used for recoupment;
- Whether and how Part D plan sponsors audit, verify, or otherwise validate the claim-level pricing data and DIR data they receive from PBMs, particularly when the PBM is affiliated with one or more network pharmacies;
- Use of audits to recoup payment based on errors, including minor errors; and
- Opportunities for corrective action; and
- Due process provisions.

F. Limitations

CMS seeks information about Part D plan sponsor restrictions or limitations on the dispensing of covered Part D drugs by network pharmacies (or any subsets of pharmacies), including the nature and prevalence of such limitations.

G. Current Regulations and Guidance

CMS seeks information about areas in current regulations or Part D program guidance related to contracting between prescription drug plans and network pharmacies that may require clarification or additional specificity. In responding to this topic, commenters should consider Part D regulations at 42 CFR part 423, the Medicare Prescription Drug Benefit Manual,[2] and any other CMS regulations or guidance relevant to the topics included in this RFI.

H. Implementation of Standards

CMS seeks information related to the implementation of reasonable and relevant standard contract terms and conditions not otherwise addressed in the topics included in this RFI. Areas of interest include—

[2] Available at: *https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/prescription-drug-benefit-manual.*

- Operational considerations, including timelines needed for Part D plan sponsors, PBMs, and pharmacies to modify contracts to comply with new standards and implement other needed operational changes;
- What documentation CMS should require to demonstrate compliance with standards for reasonable and relevant standard contract terms and conditions once finalized;
- Contracting practices not captured in this RFI that CMS should evaluate;
- Examples of pharmacy contract terms and conditions or similar frameworks that could be viewed as models;
- Criteria CMS should consider to ensure standards are transparent, objective, and enforceable.

III. Collection of Information Requirements

This is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, CMS will not respond to questions about the policy issues raised in this RFI.

CMS will consider all input as we develop future proposals or policy guidance. We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, we may publicly post the public comments received or a summary of those public comments.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 15, 2026.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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