

Issue Brief

FEDERAL ISSUE BRIEF



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CMS Proposes to Implement Key Sections of the Consolidated Appropriations Act of 2026

The Centers for Medicare & Medicaid Services (CMS) are issuing a proposed rule to amend the regulations for the Medicare Advantage (Part C) program, the Medicare Prescription Drug Benefit (Part D) program to implement section 6219 (Adjustments to Medicare Part D Cost-Sharing Reductions For Low-Income Individuals), section 6220 (Requiring Enhanced and Accurate Lists of (REAL) Health Providers Act), and section 6224 (Modernizing and Ensuring Pharmacy Benefit Manager Accountability) of the **Consolidated Appropriations Act, 2026 (CAA)**.

The rule is scheduled for publication in the **Federal Register** on October 20. A display copy of the 265-page rule is currently available at: <https://public-inspection.federalregister.gov/2026-21420.pdf>. A 60-day comment period, ending December 15 is provided.

Summary of the Key Provisions

The CAA was signed into law on February 3, 2026. In this rule, CMS is proposing to implement the following sections:

1. Adjustments to Medicare Part D Cost-Sharing Reductions for Low-Income Individuals (Section 6219 of the Consolidated Appropriations Act, 2026)

CMS is proposing to implement section 6219 of the CAA that would reduce the generic drug copayment from \$1 to \$0 for full-benefit dual eligible individuals at or below 100 percent of the Federal Poverty Level, effective for plan years starting January 1, 2028.

2. REAL Health Providers Act (Section 6220 of the Consolidated Appropriations Act, 2026)

CMS proposes to codify regulations to implement section 6220 of the CAA, titled the Requiring Enhanced and Accurate Lists of (REAL) Health Providers Act, which establishes new provider directory accuracy and accountability requirements for Medicare Advantage (MA) organizations beginning in contract year 2028. Specifically, CMS proposes requirements to implement this new law related to provider directory verification and maintenance standards, annual accuracy analysis and reporting, public reporting of accuracy scores, and cost sharing protections for enrollees who rely on inaccurate provider directory information. CMS also proposes to codify the statutory requirements for contract year 2029, including that CMS must publicly display provider directory accuracy scores in a machine-readable format and MA organizations must prominently display those scores in their provider directories. Through these proposed codifications implementing the REAL Health Providers Act, CMS seeks to promote provider directory accuracy and accountability among MA organizations to ensure

that beneficiaries are provided with clear, accurate information on the network of providers available to meet their health care needs.

3. Modernizing and Ensuring Pharmacy Benefit Manager Accountability (Section 6224 of the Consolidated Appropriations Act, 2026)

CMS has several proposals to implement section 6224 of the CAA, which established requirements related to pharmacy benefit managers (PBMs) and their affiliates specific to the Medicare Part D program. These proposals include new and enhanced requirements governing the remuneration that PBMs and their affiliates may receive for services in connection with the utilization of Part D drugs, data reporting by PBMs to Part D plan sponsors and CMS, transparency in price guarantee arrangements between PBMs or their affiliates and Part D plan sponsors, disclosure by PBMs to Part D plan sponsors of the terms of certain agreements between PBMs or their affiliates and pharmaceutical manufacturers, and other requirements added by the CAA. CMS also proposes to define key terms related to such requirements and establish compliance and enforcement mechanisms, including disgorgement of funds to CMS for violations of the remuneration requirements.

The rule does not provide a table-of-contents. We have constructed one as noted below.

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Implementing Certain Provisions of Consolidated Appropriations Act, 2026

CMS adds § 422.123 (Provider directory accuracy) and § 422.124 (cost-sharing protections), and amends §§ 422.2, 422.111, 422.120, 422.202, 422.504, 422.2265 and 422.2267. It relies on sections 1856(b)(1) and 1857(e)(1) of the Act for standards that go beyond the statute. The new requirements apply to "specified MA plans" (all network-based plans, excluding non-network regional PPOs that meet access standards through section 422.112(a)(1)(ii)).

- Definitions (§ 422.2), pp. 15-21: new definitions of "specified MA plan," "provider directory," "provider directory information" and "provider directory accuracy score."
- Verification (§ 422.123(a)-(b)), pp. 21-28: applies from contract year 2028. Providers listed in the directory must be verified at least every 90 days. *Hospitals and certain other facilities (those in § 422.116(b)(2)(i), (iv) and (v)) must be verified at least every 12 months.* CMS specifies the verification methods; the first four are internal plan information, telephone, e-mail and provider attestation. Information that cannot be verified must carry an indication that it may not be current.

New § 422.123(b)(4) would require a contract term obliging providers to supply accurate information to support verification.

- Updating (§ 422.123(c)), pp. 28-32: existing updating requirements move from § 422.2267(e)(11)(iv) into § 422.123(c)(1), and new hardcopy-directory requirements are added, including quarterly addenda.
- Annual accuracy analysis and sampling (§ 422.123(d)(1)-(2)), pp. 32-46: each MA organization estimates directory accuracy for each specified MA plan. Provider name, cultural and linguistic capabilities and common ownership or control disclosure are excluded. The sampling frame is unique provider records (provider, address and phone number). The sample is a simple random sample: 65 percent of records from any specialty other than the high-inaccuracy type, and 35 percent from specialty types with high inaccuracy rates. In this proposal the only such type is mental health and substance use disorder treatment. CMS will issue annual technical guidance and is considering stratification by county type (for example Large Metro/Metro/Micro versus Rural/ Counties with Extreme Access Considerations (CEAC). It cites its own past reviews, in which 44.29 percent of location listings (across 11,360 providers and 18,852 locations) had at least one inaccuracy.
- Accuracy score (§ 422.123(d)(3)-(4)), pp. 46-58: the score must be estimated using the specified verification methods and the sample above, with limits on which method may verify which element for scoring purposes (for example, internal plan information only for network participation and specialty). The score is weighted: network participation status 40 percent; contact information 20 percent; primary office or facility address 20 percent; specialty 10 percent; accommodations for people with disabilities 3.5 percent; telehealth capability 3.5 percent; accepting new patients 3 percent. CMS is also weighing different treatment of rural and CEAC records and plans.
- Reporting (§ 422.123(d)(5)), pp. 58-61: an annual accuracy report with a score for each specified MA plan, due the first Monday in April following the measured contract year.
- Low-enrollment exception, p. 61: the statute allows an exemption from the analysis and reporting for plans with low enrollment as defined by the Secretary. CMS is considering whether and how to use it and has not proposed a definition.
- Contract term and public transparency, pp. 62-63: new § 422.504(a)(22) makes compliance a contract obligation. From contract year 2029, CMS posts accuracy scores in a machine-readable file (CY2028 scores reported in April 2029) and is considering Application Programming Interfaces (API) access. MA organizations must display scores in their directories.
- Cost-sharing protections (§ 422.124), pp. 63-69: if an enrollee gets covered care from an out-of-network provider who was listed in the plan's directory on the date the appointment was made, the enrollee pays no more than the lesser of in-network cost sharing or the cost sharing that would otherwise apply. Plans apply the protection without an enrollee request when they know or should know it applies. Requests (verbal or written) are handled as organization determinations or reconsiderations. The appointment date is established through provider documentation (scheduling records or confirmations), then a provider attestation; if neither is obtainable the protection is applied in the enrollee's favor. Amounts count toward the in-network maximum out-of-pocket (MOOP). Directory archives must be kept for more than ten years and produced to CMS within 5 business days.

- Disclosure (§ 422.111), pp. 69-74: amends the directory and disclosure elements, including a new beneficiary disclosure requirement.
- Integration, p. 74: CMS explains how the framework fits with existing § 422.111(m), Medicare Plan Finder and the National Provider Directory (NPD). Accountability attaches to data the MA organization submits, verifies and attests to, not to elements added by the NPD from outside sources. CMS invites comment on conflicts or gaps among the three frameworks.

CMS creates new Subpart BB of Part 423 (§§ 423.2800-423.2822 and following) implementing section 1860D-12(h).

- Who is a pharmacy benefit manager (PBM) (§§ 423.2802, 423.2804), pp. 87-104: the statutory definition is functional, so an entity is a PBM based on what it does (directly or through an intermediary) regardless of its own label. CMS addresses contract requirements, related services and PBM functions, a minimum threshold for performing a PBM function, intermediaries, and Part D sponsors that perform PBM functions themselves.
- Who is an affiliate (§ 423.2806), pp. 104-119: CMS surveys ownership and control standards (party-in-interest, IRC controlled-group rules, ERISA, SEC beneficial ownership). The proposal uses ownership, functional and contractual prongs, including a brother-sister controlled group test, a 10 percent or greater capital or profits interest in a joint venture or similar entity, and a totality-of-the-relationship test.
- Remuneration rule (§ 423.2810), pp. 120-150: PBMs and affiliates may receive no remuneration for Part D drug services other than bona fide service fees. A fee must be a flat dollar amount for an itemized service actually performed that the payer would otherwise perform or contract for. It may not depend on drug price or benchmark, rebates or discounts, formulary placement, or referral volume. Only the portion of remuneration allocable to Part D utilization is subject to the rule. CMS proposes a cost-based fair market value standard (cost plus a reasonable markup, drawing on federal cost-reasonableness principles) rather than requiring independent third-party valuers, and proposes to prohibit certain fee methodologies that would force bundled services.
- Incentive payments, pp. 141-142: limited performance-based payments from the Part D sponsor, with a fair market value standard distinct from the one for service fees.
- Price concessions exception, pp. 142-146: manufacturer rebates, discounts and other price concessions (even percentage-based) are permitted if fully passed through, defined as the sponsor receiving 100 percent of the gross economic value, with no netting, offsets, retention or deductions such as administrative, data or aggregation fees. Compliance with direct and indirect remuneration (DIR) requirements is addressed, and a sponsor acting as its own PBM is deemed to meet pass-through if it receives 100 percent of the value.
- Disgorgement (pp. 150-152, 172-174): remuneration received in violation must be disgorged to the Part D sponsor, generally within 30 days of the end of a sponsor audit or of the PBM's own identification. CMS also addresses disgorgement to CMS, civil money penalty pass-through, punitive remedies, reporting of violations, anti-retaliation and anti-coercion, and CEO/CFO/GC-level certifications of compliance.

- Evaluation of remuneration agreements, pp. 152-157; price guarantee transparency (§ 423.2812), pp. 157-160: PBMs must give sponsors a WAC-based equivalent of any pricing guarantee and disclose the WAC source. Effective-rate guarantees with pharmacies are not addressed here but may come in future rulemaking.
- Annual PBM reporting (§ 423.2814), pp. 160-169: reports to sponsors and CMS by July 1 each year beginning 2028, in a machine-readable format CMS will specify by June 1, 2027 through program instruction. The report is certified by the CEO, CFO or General Counsel (or a delegate). Required content covers drug lists with NADAC and reimbursement data, pharmacy information, reference listed drugs and generics, reference products and biosimilars, PBM-retained revenue, and brokers, consultants, advisors and auditors. The statute exempts this reporting from the Paperwork Reduction Act.
- Manufacturer agreements (§ 423.2816), p. 169; audit rights (§ 423.2818), pp. 170-172: PBMs provide written explanations of manufacturer arrangements. Sponsors may audit; the PBM must produce information within 6 months of audit initiation and answer follow-up requests within 30 days, including information held by affiliates.
- Confidentiality (§ 423.2822), pp. 175-177; severability, p. 177.

Regulatory Impact

- Part D copay elimination: net federal cost of about \$1.337 billion over 2028-2037, built from a \$1.461 billion increase in program spending less a \$124 million premium offset. CMS treats the copay elimination as a transfer rather than a cost.
- REAL Health Providers Act: increased administrative and compliance costs for MA organizations. Overall rule costs are described as de minimis, about \$6 million in 2028 and about \$1.6 million in later years, below the HHS significance threshold.
- PBM provisions: financial impact cannot be estimated because of limited data on PBM contract structures and on the gap between current fees and the proposed fair market value. CMS cites a CBO estimate that the statute reduces federal direct spending by about \$444 million over 2026-2035.
- Other: alternatives considered for each REAL Health Providers Act element (pp. 203-207), regulatory review cost estimate, accounting statement, RFA small-entity analysis, UMRA and federalism, and E.O. 14192 (about \$1.4 million annualized at 7 percent).

Final Thoughts

While CMS says this rule is aimed at MA organizations prescription drug entities, CMS says that “hospitals and certain other facilities (those in § 422.116(b)(2)(i), (iv) and (v)) must be verified at least every 12 months.” It will be interesting to see if CMS clarifies applicable entities in its final rule.

CMS appears to downplay the cost of this program. The proposal does contain some numbers, but one would assume this is going to be a costly issue.