
42 C.F.R. § 403.806

Sponsor requirements for eligibility for endorsement.

Except as specified in §§ 403.814, 403.816, and 403.817, an endorsed sponsor must meet the following requirements:

- (a) *Applicant experience.* (1) An applicant must be a non-governmental, single legal entity doing business in the United States.
 - (2) An applicant must have 3 years of private sector experience in the United States in pharmacy benefit management, which is defined to mean —
 - (i) Adjudicating and processing claims for drugs at the point of sale;
 - (ii) Negotiating with prescription drug manufacturers and others for discounts, rebates, and/or other price concessions on prescription drugs; and
 - (iii) Administering and tracking individuals' subsidies or benefits in real time.
 - (3) A single legal entity which is either the applicant or a subcontractor must, at the time of application for Medicare endorsement, operate a pharmacy benefit program, a prescription drug discount card program, a low-income drug assistance program, or a similar program that serves at least 1 million covered lives.
 - (b) *Financial stability and business integrity.* (1) An applicant must demonstrate a satisfactory record of the financial stability and business integrity of itself, any subcontractors on whom the applicant relies to satisfy the 3 years experience requirement in paragraph (a)(2) of this section and the 1 million covered lives requirement in paragraph (a)(3) of this section, and any subcontractors engaged by the applicant to perform the following activities: develop the pharmacy network; negotiate with manufacturers or pharmacies for rebates, discounts, or other price concessions; handle eligibility for or enrollment in the endorsed sponsor's endorsed discount card program and/or transitional assistance; and administer transitional assistance.
 - (2) An endorsed sponsor and any subcontractors described in paragraph (b)(1) of this section must maintain a satisfactory record of financial stability and business integrity during the term of the endorsed program.
 - (3) Medicare endorsement of a discount card program shall not be construed to express or imply any opinion that an endorsed sponsor or any subcontractor of an endorsed sponsor is in compliance with or not liable under the False Claims Act, anti-kickback statute (section 1128B(b) of the Act), or other legal authorities for any improper billing, claims submission, or related conduct.
 - (c) *Compliance with applicable law.* An endorsed sponsor must comply with all applicable Federal and State laws, including the Federal anti-kickback statute (section 1128B(b) of the Act).
 - (d) *Prescription drug offering.* An endorsed sponsor must comply with the following discount, rebate, and
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formulary requirements:

- (1) Offer all of its discount card enrollees negotiated prices on covered discount card drugs, which may be limited to those covered discount card drugs included on the endorsed sponsor's formulary.
- (2) If the endorsed sponsor uses a formulary, offer a negotiated price on at least one covered discount card drug in each of the lowest level categories for each of the therapeutic groups representing the drugs most commonly needed by Medicare beneficiaries as determined by CMS. A specific covered discount card drug may not be used to fulfill this requirement for more than one category.

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