

### c. Demonstration of Financial Stability and Business Integrity

As required by section 1860D–31(h)(1)(B) of the Act, and as provided for in § 403.806(b)(1) of our regulations, an applicant must demonstrate the financial stability and business integrity of itself, and any of its subcontractors on which the applicant relies to—

- (1) Develop the pharmacy network;
- (2) Handle the negotiation of drug rebates or discounts;
- (3) Administer enrollment, including transitional assistance eligibility determinations;
- (4) Administer transitional assistance; or
- (5) Meet the 3-years of experience and/or covered lives requirements.

The application should include the following documents or information for the applicant and each of these subcontractors:

- A summary of the entity's history, structure, and ownership, including a chart showing the structure of ownership, subsidiaries, and business affiliations;
- The most recent audited financial statements (balance sheet, income statement, statement of cash flow along with auditor's opinions, and related footnotes), which must demonstrate that the entity's total assets are greater than total unsubordinated liabilities and that the entity has sufficient cash flow to meet its obligations as they come due;
- Financial ratings, if any, for the past 3 years; and
- Listing of past or pending investigations (if known to the entity) and legal actions brought against the entity (and its parent entities, if applicable) by any financial institution, government agency (local, State, or Federal), or private organization over the past 3 years on matters relating to health care and prescription drug services and/or allegations of fraud, misconduct, or malfeasance. The application should include a brief explanation of each action, including the following: (1) Circumstances giving rise to the action; (2) the action's status (pending or closed); and (3) if closed, details as to resolution of the action and any monetary damages.

Additionally, we plan to conduct an independent investigation of each entity, with respect to the above factors, which will include a review of Federal databases available to us that may contain information pertaining to legal issues involving the entity.

In deciding whether to endorse an applicant with a record of legal actions brought against it, we will evaluate that record based on factors that include: (1)

Whether the action is a pending investigation or has resulted in a settlement or judgment against the applicant, (2) whether the settlement or judgment has been issued recently (for example, within the past 3 years), (3) whether the conduct on which the judgment or settlement was based involved allegations of fraud or abuse, (4) whether the conduct was related to reimbursement for health care services or products, and (5) whether the applicant is currently operating under a corporate integrity agreement with the DHHS Office of the Inspector General.

We require the applicant to demonstrate the business stability and integrity of the applicant and these subcontractors to ensure that we endorse only those endorsed sponsors that will be reliable, stable, and operate with integrity. We believe the specific requirements are an appropriate method for determining the business integrity and financial stability of an applicant and its subcontractors. For example, by requiring that assets exceed liabilities, we increase the likelihood that an endorsed sponsor will remain in the Medicare drug discount card program for the life of the program. Similarly, reviewing financial ratings and past or pending investigations allows us to represent to our beneficiaries that we have endorsed applicants that are financially sound and committed to a high level of business integrity.

As discussed elsewhere in this document, an applicant that is a Medicare managed care organization offering an exclusive card program will be deemed to have met these business stability and integrity requirements through its compliance with § 422.400, if a Part C plan, or §§ 417.120 and 417.122, if a Medicare cost plan.

Following its receipt of endorsement, as provided in § 403.806(b)(2) of our regulations, an endorsed sponsor (including both the applicant and its subcontractors) must continue to operate with fiscal stability and business integrity, in accordance with the same standards applicable to the applicant. Also, we require at § 403.806(c) that endorsed sponsors comply with all applicable Federal and State laws, including the Federal anti-kickback statute, section 1128B(b) of the Act (42 U.S.C. 1320a–7b(b)). As provided in § 403.806(b)(3) of our regulations, Medicare endorsement of a discount card program shall not be construed to express or imply any opinion that an endorsed sponsor or any subcontractor is in compliance with or not liable under the False Claims Act, Federal anti-kickback statute, or other laws, regulations, or policies regarding

improper billing, claims submission, or related conduct.

### d. Contracts With Subcontractors and Pharmacies

Although only one legal entity may act as the applicant, our regulations at § 403.804(c)(1) permit applicants to combine their capabilities with other entities in order to meet the requirements for Medicare endorsement. As will be further described in the solicitation, applicants must include documentation, including contracts or signed letters of agreement, related to their legal arrangements with these subcontractors if the applicant has combined with such entities to meet the following requirements—

- Years of experience and/or covered lives;
- Establishing a pharmacy network or home delivery through mail order;
- Negotiating manufacturer discounts or rebates;
- Conducting enrollment and transitional assistance eligibility;
- Administering transitional assistance;
- Operating the customer service call center;
- Administering a grievance process; and
- Developing information and outreach materials.

The contracts or signed letters of agreement must—

- Clearly identify the parties to the contract;
- Describe the functions to be performed by the subcontractor;
- Contain language indicating that the subcontractor has agreed to participate in the Medicare drug discount card program (except for a network pharmacy if the existing contract would allow participation in this program);
- Describe any payment the subcontractor will receive under the contract;
- Extend for the lifetime of the Medicare drug discount card program;
- Be signed and executed by representatives of each party with legal authority to bind the party;
- Require the subcontractor to comply with State and Federal privacy and security requirements applicable to the endorsed sponsor or the subcontractor, and our marketing and document retention requirements, including the requirements provided in § 403.812 and § 403.813 of our regulations and discussed in section II.C.9. of this document.

In addition, as will be further explained in the solicitation, an endorsed sponsor also must include in