

card program must provide a system to reduce the likelihood of medication errors and adverse drug interactions and to improve medication use (section 1860D–31(e)(2) of the Act). Endorsed sponsors have flexibility to design their own individual systems to accomplish these goals. We will require applicants to describe their systems and discuss how these goals will be accomplished. Published scientific and clinical literature should support the proposed approaches. If applicants have experience using their proposed systems to accomplish these goals, applications should describe past achievements in reducing medication errors and adverse drug interactions and in improving medication use.

#### 8. Grievance Process

Section 1860D–31(h)(5) of the Act specifies that endorsed sponsors must establish and maintain a grievance process to track and address in a timely manner enrollees' complaints about any aspect of the endorsed sponsor's operations. The grievance process does not include the reconsideration process, described in section 1860D–31(f)(4) of the Act and discussed in section II.A.5. of this document, which affords beneficiaries an opportunity to seek review of an initial determination that they are ineligible to receive transitional assistance or enroll in an endorsed program.

A grievance is any card enrollee's complaint or dispute expressing dissatisfaction with the manner in which he or she has received services under an endorsed program. The subjects of a grievance may include the timeliness, appropriateness, access to, and/or setting of services provided by the endorsed sponsor, such as waiting times, demeanor of pharmacy or customer service staff, or disrespect shown a card enrollee. A grievance may also include a dispute concerning the endorsed sponsor's failure to offer discounts on particular covered discount card drugs, ensure its pharmacies charge a certain price for covered discount card drugs, apply transitional assistance toward the cost of a covered discount card drug obtained by a transitional assistance enrollee under the program, or correctly calculate the correct coinsurance amount for a covered discount card drug obtained by a transitional assistance enrollee.

In § 403.806(j) of our regulations, we require endorsed sponsors to maintain meaningful procedures for timely review and resolution of their card enrollees' grievances. We will publish more specific guidelines on grievance

procedures in our solicitation. These guidelines will include the following features—

- (1) Endorsed sponsor's ability to collect information concerning the grievance;
- (2) Timely transmission of grievances to appropriate decision-making levels within the endorsed sponsor's organization, including to any subcontractors;
- (3) Taking prompt and appropriate action to address a grievance, including conducting a full investigation of the grievance if warranted; and
- (4) Communication of the results of an investigation to all concerned parties, consistent with applicable State law.

#### 9. HIPAA Administrative Simplification Provisions and Other Marketing and Security Provisions

##### a. General

Section 1860D–31(h)(6)(A) of the Act provides that for the purpose of the Medicare drug discount card program, the operations of an endorsed program are covered functions and an endorsed sponsor is a covered entity for purposes of applying Part C of title XI and all regulatory provisions promulgated thereunder, including regulations (relating to privacy) adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We therefore provide in § 403.812(a) of our regulations that endorsed sponsors are covered entities and must comply with the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164 as set forth in § 403.812 of our regulations. Section 403.812(a) of our regulations also provides that those functions of an endorsed sponsor the performance of which are necessary or directly related to the operations of the endorsed discount card program are covered functions for purposes of applying to endorsed sponsors the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164.

Section 1860D–31(h)(7)(B) of the Act provides that an endorsed sponsor only may market those products and services under its endorsed program that are directly related to a covered discount card drug, or discounts on non-prescription drugs to the extent such marketing is otherwise permitted under the Medicare discount drug card program, and the use of beneficiary information for such communications is permitted by the HIPAA Privacy Rule.

#### b. Overview of HIPAA Administrative Simplification Regulations

The HIPAA Administrative Simplification Regulations are a suite of regulations that provide for the standardization of certain electronic financial and administrative health care transactions, as well as for the privacy and security of individually identifiable health information.<sup>4</sup> The regulations apply to three types of entities, which collectively are termed "covered entities"—health care providers who transmit protected health information in electronic form in connection with a transaction for which the Secretary has adopted a standard, health plans, and health care clearinghouses. Section 1860D–31(h)(6)(A) of the Act essentially specifies a fourth type of covered entity, the endorsed sponsors. Therefore, as a condition of endorsement, endorsed sponsors must comply with the HIPAA Administrative Simplification regulations in the manner described in § 403.812 of our regulations.

Section 1860D–31(h)(6)(A) of the Act provides that only the endorsed sponsor's operations of an endorsed program are covered functions. Consequently, activities performed by an endorsed sponsor outside of the scope of its endorsement under the Medicare drug discount card program are not made covered functions by the Act. However, if these other activities would make the endorsed sponsor a health plan, covered health care provider, or health care clearinghouse, as currently defined by HIPAA, then the endorsed sponsor may otherwise be a covered entity that is subject to the Administrative Simplification regulations. An endorsed sponsor performing non-covered functions may declare itself a hybrid entity in accordance with 45 CFR 164.105, with its health care component including any component performing operations that make the entity an endorsed sponsor.

As provided in § 403.812(f) of our regulations, nothing in this discussion or § 403.812 of our regulations should be considered a modification of the HIPAA Administrative Simplification regulations or as otherwise affecting the applicability of the Administrative Simplification regulations to covered entities other than endorsed sponsors. Moreover, as provided in § 403.812(f) of our regulations, if an endorsed sponsor is also a health plan, covered health care provider, or health care clearinghouse, the Administrative Simplification

<sup>4</sup> The suite includes regulations for the electronic health care transactions and code sets, unique health identifiers for health plans, health care providers, and employers, and security and privacy.