

performance, use of prescription drugs by discount card enrollees, the extent to which discounts, rebates or other remunerations or price concessions made available to the endorsed sponsor by a manufacturer are passed through to discount card enrollees through pharmacies or otherwise, and such other information as the Secretary may specify. As provided under these authorities and in order to promote and protect the interests of beneficiaries, endorsed sponsors are required to maintain for auditing purposes, data and other information that will accomplish oversight objectives.

Additionally, we will collect information as part of our education and outreach efforts described in Section II.E, to provide beneficiaries comparative prices on covered discount card drugs across all endorsed programs.

To meet these objectives, we specifically require in § 403.806(i) of our regulations that endorsed sponsors report certain types of information. Examples include:

- Savings obtained through rebates, discounts, and other price concessions from pharmacies and manufacturers;
- Savings shared with discount card enrollees by manufacturer, by all retail pharmacies, by all mail order pharmacies, and by all brand name and generic covered discount card drugs;
- Dispensing fees;
- Certified (by the chief financial officer) financial accounting records on transitional assistance used by the transitional assistance enrollees in each month;
- Participant utilization and spending statements;
- Performance on customer service metrics such as call center performance;
- Grievance logs;
- Compliance with the pharmacy network access standards; and
- Notice of, and the rationale for, negotiated price increases, except for increases during the week of November 15, 2004, due to reasons other than changes in average wholesale price (AWP), including submission of an attestation that, based on best knowledge, information, and belief, the rationale for the price increase is accurate, complete, truthful, and supportable.

In addition, to support our education and outreach efforts endorsed sponsors must report the following—

- Customer service hours,
- Customer service contact information,
- Endorsed program Web site address,
- Annual enrollment fee, and

- Negotiated prices (including any applicable dispensing fee) for every covered discount card drug included in the endorsed program's offering.

This is not an exhaustive list of the types of card program performance we will monitor and evaluate, as we will, as described in section II.F. of the preamble, also conduct activities independent of this information to, for example, monitor whether marketing materials are properly used; evaluate beneficiary experience under the endorsed programs; and conduct program integrity activities.

The data and information that endorsed sponsors will be required to report consist of performance measures and indicators typically provided by third party administrators of pharmacy benefits in the current drug industry. Endorsed sponsors must certify the validity and completeness of the data and other information they report.

Further, during the endorsement period, endorsed sponsors will be required to notify us of any material modifications to their endorsed programs if the modification could put them at risk of no longer meeting any of the terms of the endorsement.

Section 1860D–31(i)(1) of the Act provides that section 1927(b)(3)(D) of the Act, which guides the protection of proprietary pricing information under the Medicaid program, shall also apply to the drug pricing data (other than aggregated data) under the Medicare drug discount card program. Consistent with the requirements of 1927(b)(3)(D) of the Act, we will handle any non-aggregated pricing information in a manner that ensures that the non-aggregated discounts or rebates or other remuneration or price concessions from manufacturers to endorsed sponsors, and reported by the endorsed sponsors, will not be made available in a format that discloses the identity of particular drugs, manufacturers, or wholesalers. However, the information may be disclosed in the circumstances described in section 1927(b)(3)(D)—

- (1) As the Secretary deems necessary to carry out section 1860D–31 of the Act;
- (2) To permit the Comptroller General to review the information provided; and
- (3) To permit the Director of the Congressional Budget Office to review the information provided.

We will provide a reporting tool to ensure consistent and comparable reporting by endorsed sponsors. In developing the tool, we will make an effort to minimize the reporting burden on endorsed sponsors.

D. CMS Reimbursement of Transitional Assistance

All endorsed sponsors must enter into an agreement with CMS that will provide for reimbursement from CMS to endorsed sponsors for any transitional assistance applied toward the cost of covered discount card drugs obtained by transitional assistance enrollees in accordance with section 1860D–31(g)(3) of the Act. Under the contract, sponsors will submit requests to debit each enrollee's transitional assistance balance via the Department of Health and Human Services' Payment Management System. These amounts will be reported to CMS and used to reconcile payments, as provided in § 403.822(c) of our regulations.

Endorsed sponsors will be required to submit monthly reports detailing the total amount of transitional assistance applied toward the cost of covered discount card drugs obtained by transitional assistance enrollees. These reports will be reconciled against transitional assistance balance reports used to authorize payments to endorsed sponsors.

Endorsed sponsors will only be reimbursed for transitional assistance applied toward the cost of covered discount card drugs for claims that are fully adjudicated for payment; we will not reimburse endorsed sponsors for pending claims. Further, as provided in § 403.822(e) of our regulations, Federal funding in excess of the amount of the balance included in CMS' systems is not permitted.

We also expect endorsed sponsors to establish a process for holding pharmacies harmless, that is reimbursing pharmacies for their costs if the endorsed sponsor erroneously informs the pharmacy that the amount of transitional assistance remaining available to a transitional assistance enrollee is more than the amount actually available to the transitional assistance enrollee.

As discussed above in section II.C.6. of this document, should a discount card enrollee be determined eligible for transitional assistance after already enrolling in an endorsed program, we will pay the annual enrollment fee and the endorsed sponsor must immediately refund to the card enrollee, or any State that has paid the enrollment fee on behalf of the discount card enrollee, any annual enrollment fee for the calendar year previously paid by the discount card enrollee or State. The endorsed sponsor would include this payment in its report to us for our reimbursement.

Endorsed sponsors will be required to have a process for managing payment