

covered discount card drugs obtained under the program; and

- Track the amount of transitional assistance available to each transitional assistance enrollee.

We understand that in some circumstances real-time claims adjudication may not be possible, for instance, due to coordination of benefits issues. To accommodate these circumstances, endorsed sponsors must have the capacity to process claims off-line for transitional assistance.

As discussed below in section II.G. of this document, exclusive card sponsors may permit their transitional assistance enrollees to apply transitional assistance toward any copayments, coinsurance, and deductible amounts for covered discount drug cards obtained under their Medicare managed care plan outpatient drug benefit. Medicare managed care organizations seeking to offer an exclusive card program must indicate in their applications their intent to permit transitional assistance enrollees to apply transitional assistance toward the cost of covered discount card drugs obtained under their Medicare managed care plan and explain their process for doing so.

Applicants must include in their applications details on their proposed methods for managing and accounting for transitional assistance.

As discussed in section II.C.6. of this document, endorsed sponsors will not be permitted to charge their transitional assistance enrollees any annual enrollment fee; rather, we will pay any enrollment fee on their behalf.

Endorsed sponsors will be required to establish procedures for applying transitional assistance toward the cost of covered discount card drugs obtained by transitional assistance enrollees under the Medicare drug discount card program. Such procedures must include applying the coinsurance rules set forth in section 1860D–31(g)(1)(B) of the Act, as stated in § 403.808(e) of our regulations and discussed in section II.A.4.a. of this document. Further, as stated in § 403.806(e)(6) of our regulations, endorsed sponsors must ensure that transitional assistance is not applied to cover the portion of the negotiated price that transitional assistance enrollees are responsible for paying under the coinsurance rules. That is, endorsed sponsors must ensure that the amount of transitional assistance applied toward the cost of covered discount card drugs obtained by transitional assistance enrollees is the negotiated price (or usual and customary price, if lower) minus the coinsurance. For example, if a beneficiary has a \$600 transitional

assistance balance and he or she obtains a covered discount card drug under the Medicare drug discount card program with a negotiated price of \$100, the beneficiary would pay, depending on his or her income, a coinsurance of 5 percent or 10 percent (\$5 or \$10), the endorsed sponsor would pay the negotiated price minus the coinsurance amount (\$95 or \$90), and following the transaction, the amount of transitional assistance remaining available to the transitional assistance enrollee would be \$505 or \$510. In their applications, applicants must describe their approach for applying the coinsurance rules.

Section 101(e)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 exempts from the prohibition under section 1128B(b)(3) of the Act pharmacies who waive or reduce coinsurance for enrollees with transitional assistance provided such waiver or reduction meets the conditions in clauses (i) through (iii) of section 1128A(i)(6)(A). Thus, pharmacies participating in an endorsed program's network could not be criminally prosecuted under section 1128B(b)(3) of the Act for waiving or reducing coinsurance under the Medicare drug discount card program provided the pharmacies comply with the provisions of clauses (i) through (iii) of section 1128A(i)(6)(A) of the Act, which include the following—

- The waiver is not to be advertised;
- The coinsurance is not routinely waived; and
- The coinsurance is waived only after determining (in good faith) that—
- The eligible beneficiary is in financial need; or
- The pharmacy has made reasonable collection efforts but still failed to collect the coinsurance due.

Pharmacies and endorsed sponsors seeking further guidance regarding waivers or reduction of coinsurance may request advisory opinions from the Office of the Inspector General. To request an advisory opinion, entities should submit an original and 2 copies of a written request that contains certain specified information to the following address:

Chief, Industry Guidance Branch, U. S. Department of Health and Human Services, Office of Inspector General, Office of Counsel to the Inspector General, Room 5527, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

For more information on the advisory opinion process and the information included in the request, please refer to [www.oig.hhs.gov/fraud/advisoryopinions.html](http://www.oig.hhs.gov/fraud/advisoryopinions.html).

In addition, as discussed under section II.H. of this document, States may establish arrangements to pay directly to endorsed sponsors some or all of the coinsurance on behalf of transitional assistance enrollees in their State. If a pharmacy waives or reduces a transitional assistance enrollee's coinsurance amount or if the State pays some or all of the coinsurance, the endorsed sponsor must ensure that no more than 90 or 95 percent, as applicable, of the negotiated price is paid using transitional assistance funds.

#### 5. Products and Services Inside and Outside the Scope of the Endorsement

Section 1860D–31(e)(1)(C) of the Act prohibits an endorsed discount card sponsor (and any pharmacy included in the endorsed sponsor's network) from charging card enrollees any amount, other than the annual enrollment fee and negotiated prices (which include dispensing fees), for any items and services required to be provided by the endorsed sponsor under the Medicare drug discount card program. Therefore, our regulations at § 403.806(h)(2) prohibit endorsed sponsors (and their network pharmacies) from charging any amount for required services other than the enrollment fee and negotiated prices. Required services include, for example—

- Conducting enrollment;
- Offering negotiated prices on covered discount card drugs;
- Ensuring convenient pharmacy access;
- Reducing the likelihood of medication errors and adverse drug interactions;
- Providing customer service and information and outreach materials;
- Providing a grievance mechanism; and
- Administering transitional assistance.

Section 1860D–31(h)(7)(A) of the Act allows endorsed sponsors to provide certain non-required services under their endorsements as well, but only if such products or services are directly related to a covered discount card drug, or are discounts for over-the-counter drugs (that is, non-prescription drugs). Thus, endorsed sponsors may voluntarily choose to provide under their Medicare endorsement discounts on over-the-counter drugs, and products or services that are related to covered discount card drugs but which are not required services under the Medicare drug discount card program. For example, an endorsed sponsor might offer discounts on durable medical equipment that is related to a covered