

income card enrollees, or card enrollees with a particular disease. We believe this flexibility promotes the objective of improving beneficiaries' access to prescription drug discounts by allowing card sponsors to structure formularies and prices for these populations for whom prescription drug expenses are a significant burden. An endorsed sponsor choosing to incorporate this flexibility into its endorsed program must ensure that its alternative offerings do not restrict any card enrollee's access to its basic option should the card enrollee not wish to participate in the alternative offering.

Further, CMS recognizes that endorsed sponsors may change their negotiated prices over time for legitimate business purposes. However, because beneficiaries are generally locked into the endorsed program of their choice for a calendar year, we would not want beneficiaries to enroll in cards with unrealistically low advertised prices, only to see those prices arbitrarily increase in subsequent weeks or months. Therefore, as provided in § 403.806(d)(9) of our regulations, we require that, except during the week of November 15, 2004, (which coincides with the beginning of the annual coordinated election period), endorsed sponsors must ensure that any increase in the negotiated price does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to the changes in the endorsed sponsor's cost structure, including material changes to any discounts, rebates, or other price concessions the endorsed sponsor receives from a pharmaceutical manufacturer or pharmacy. We will monitor whether negotiated prices decline in proportion to decreases in AWP.

As discussed in section II.C.7. of the document, an endorsed sponsor must make available to its card enrollees, over its customer service telephone line, upon request, information about negotiated prices.

Under section 1860D–31(h)(8) of the Act, and as provided in § 403.806(d)(7) of our regulations, endorsed sponsors must ensure that card enrollees are charged at the point of sale the lower of the negotiated price or the pharmacy's usual and customary price for a covered discount card drug. We expect an endorsed sponsor to arrange with its network and mail order pharmacies that if, at time of purchase, a drug's usual and customary price is lower than the negotiated price under the endorsed sponsor's endorsed program, the pharmacy will make available to card

enrollees the lower usual and customary price.

Additionally, as provided in section 1860D–31(d)(3) of the Act and stated in § 403.806(d)(8) of our regulations, endorsed sponsors are required to ensure that pharmacies inform card enrollees of any differential between the price of the covered discount card drug to the card enrollee and the price of the lowest priced generic drug that is therapeutically equivalent and bioequivalent and available at that pharmacy. This information must be provided at the time the card enrollee purchases the drug, or in the case of drugs purchased by mail order, at the time of delivery of that drug. As permitted under sections 1860D–31(d)(3)(B) and 1860D–31(g)(5) of the Act, for the reasons discussed in section II.I. of this document, we exempt from this requirement covered discount card drugs obtained from long-term care pharmacies or I/T/U pharmacies.

As provided in section 1860D–31(e)(1)(D) of the Act, the prices negotiated for covered discount card drugs under an endorsed discount card program (notwithstanding any other provision of law) will not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C) of the Act. Section 103(e) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amends section 1927(c)(1)(C)(i) of the Act by adding a new subparagraph (V) to exclude from best price any negotiated prices charged under an endorsed program. This exemption applies only to prices obtained from a drug manufacturer for the ingredient cost of the drug under the Medicare drug discount card program; prices negotiated for discount cards that are not Medicare endorsed programs would not meet the criteria of the exemption. Furthermore, since this rule relates to the Medicare drug discount card program, the rule does not address application of the best price rules to non-endorsed drug discount cards. We will not codify into regulation the statutory exemption from best price for negotiated prices under endorsed programs because we do not currently have regulations implementing section 1927(c)(1) of the Act.

d. Transitional Assistance

As discussed under section II.A. of this document, certain low-income Medicare beneficiaries enrolled in the Medicare drug discount card program will be eligible to receive transitional assistance of up to \$600 per year, which may be applied toward the cost of

covered discount card drugs obtained under the program.

Section 1860D–31(h)(1)(C) of the Act requires endorsed sponsors to administer the transitional assistance on our behalf and to demonstrate to the Secretary that they have satisfactory arrangements that account for the transitional assistance provided to transitional assistance enrollees. Therefore, as stated in § 403.806(e) of our regulations, endorsed sponsors must:

- Establish accounting procedures to manage the transitional assistance funds;
- Ensure that transitional assistance is applied toward the lower of a covered discount card drug's negotiated price (if any) or usual and customary price;
- Permit transitional assistance enrollees to apply transitional assistance toward the cost of any covered discount card drug obtained under the endorsed sponsor's endorsed program, regardless of whether that drug is on the endorsed sponsor's formulary (if any) or whether a discount has been negotiated for that drug.
- As required under section 1860D–31(d)(2)(C) of the Act, make available electronically or by telephone at the point-of-sale of covered discount card drugs the amount of transitional assistance remaining available to the transitional assistance enrollee; and
- As required under section 1860D–31(d)(2)(B) of the Act and discussed in section II.C.7. of this document, endorsed sponsors should inform transitional assistance enrollees of the endorsed sponsor's toll-free telephone number where they can obtain information on the amount of transitional assistance available to them.

In tracking the amount of transitional assistance available to transitional assistance enrollees, endorsed sponsors must take into account that any transitional assistance remaining available to a beneficiary on December 31, 2004 should be rolled over to 2005 and applied toward the cost of covered discount card drugs obtained under the program during 2005, and any transitional assistance remaining available to a beneficiary on December 31, 2005 may be applied toward the cost of covered discount card drugs obtained under the program during the transition period.

Endorsed sponsors must maintain a real-time claims adjudication system that, among other capabilities, will—

- Communicate to pharmacies the applicable coinsurance rates— 5 percent or 10 percent;
- Ensure that transitional assistance is applied only toward the cost of