

In the interest of protecting beneficiaries' health, we believe there are several issues applicants should consider in developing their formularies, if they plan to use one. First, there are several medications that are not widely recommended for use in the elderly population based on their potential to cause adverse outcomes (Beers MH. Explicit criteria for determining potentially inappropriate medication use by the elderly. *Arch Intern Med.* 1997; 157:1531–1536). However, under certain clinical conditions, some of these medications may be appropriate for use in the elderly population. Endorsed sponsors should evaluate whether or not to include these drugs on their formularies, as well as ways in which to help reduce the potential for adverse drug reactions, described further in section II.C.7. of this document.

Second, another key area for consideration by endorsed sponsors is the importance of ensuring that negotiated prices are available to special populations. Certain groups, such as beneficiaries who are HIV positive, beneficiaries with a mental illness, and beneficiaries with cancer may require treatment with a variety of specific medication combinations, which may not be easily substitutable. The medical treatment of these beneficiaries and other special populations may be significantly compromised if discounts are not made available on particular medications that they require.

Finally, we believe endorsed sponsors should consider ensuring that there are appropriate selections and dosage forms of drugs within each class or subclass as needed (for example, long-acting versus short-acting). In some cases, this might require more than one drug to satisfy a single subclass or group. Specifically, there are several therapeutic classes that contain both short-acting and long-acting medications. These medications commonly come in both standard oral dosage forms and time-release dosage forms.

We are requesting that applicants address these issues in their applications if they will use a formulary so that we may have a fuller understanding of how drug discount card programs will address the needs of Medicare beneficiaries.

c. Pricing

As provided in sections 1860D–31(e)(1)(A) and 1860D–31(h)(4) of the Act, and cited in § 403.806(d)(1) of our regulations, each endorsed sponsor will be required to provide card enrollees access to negotiated prices on covered discount card drugs. Section 1860D–

31(e)(1)(A)(ii) of the Act defines negotiated prices as taking into account negotiated price concessions (such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations) for covered discount card drugs, and includes any dispensing fees for such drugs. Thus, as a general matter, to the extent discounts, rebates, subsidies or other price concessions are obtained by endorsed sponsors, the negotiated prices must take these concessions into account and some of the concessions should be shared with beneficiaries in the form of lower prices.

In addition, section 1860D–31(i) of the Act specifically requires that endorsed sponsors disclose to us the percentage of manufacturer price concessions or rebates passed on to Medicare beneficiaries, with section 1860D–31(h)(4) of the Act requiring endorsed sponsors to pass these savings on to card enrollees. We interpret these provisions as reflecting Congressional intent that endorsed sponsors meet the threshold of obtaining some level of manufacturer rebates, discounts, or other price concessions on some covered discount card drugs. In addition, we believe requiring endorsed sponsors to obtain manufacturer rebates, discounts, or other price concessions on some covered discount card drugs will promote and protect the interests of Medicare beneficiaries.

Therefore, as stated in § 403.806(d)(6) of our regulations, as a condition of endorsement, endorsed sponsors must obtain manufacturer rebates, discounts, or other price concessions on at least some covered discount card drugs.

In requiring endorsed sponsors to disclose to us the extent to which they pass through to card enrollees manufacturer discounts, rebates or other remunerations or price concessions, section 1860D–31(i) of the Act anticipates that endorsed sponsors might not pass through to card enrollees 100 percent of such manufacturer price concessions. We therefore interpret section 1860D–31(h)(4) of the Act as requiring endorsed sponsors to pass through to card enrollees some, but not necessarily all, of these price concessions. Rather than establish minimum quantitative requirements for either the level of manufacturer rebates, discounts, or other price concessions endorsed sponsors must obtain or the share of such price concessions that must be passed through to card enrollees, we will allow endorsed sponsors to determine this in light of their understanding of consumer preferences and the impact of market forces on their business model. Research conducted for us has shown that

pharmacy benefit managers frequently obtain and pass through substantial manufacturer rebates for their commercial populations (BoozAllenHamilton, *Pharmaceutical Industry Scan*, August 6, 2002). In addition, we believe that market competition will encourage endorsed sponsors to pass through to enrollees a high percentage of the rebates, discounts, or other remuneration or price concessions. In particular, our price comparison Web site, discussed in greater detail in section II.E. of this document, will promote competition by allowing beneficiaries to compare maximum negotiated prices for drugs under different endorsed programs. Further, as described below, endorsed sponsors' negotiated prices for covered discount card drugs will not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C) of the Act. We therefore anticipate that endorsed sponsors will pass a substantial share of manufacturer price concessions through to beneficiaries in the form of negotiated prices at the point of sale. We have chosen not to establish minimum threshold levels for manufacturer price concessions because doing so could have the unintended effect of undercutting market competition as endorsed sponsors might cluster their drug price offering around that threshold.

We believe this approach provides endorsed sponsors with maximum flexibility within the basic program requirement in designing their endorsed program and negotiating price concessions with a broad range of manufacturers at levels that are commensurate with the structure of their endorsed programs.

In recognition of current industry practice, we anticipate that the level of discount offered to card enrollees will vary across the full complement of covered discount card drugs offered at negotiated prices. Moreover, as provided in § 403.806(d)(4) of our regulations, prices may vary across pharmacy contracts. We believe it is necessary to permit such price variation in order to provide endorsed sponsors sufficient flexibility to accommodate local market conditions and competition. As part of our educational efforts, we will explain to beneficiaries the possibility of price variation by pharmacy, and expect endorsed sponsors to do the same.

Additionally, we will allow endorsed sponsors to vary prices and formularies by enrollee characteristics, such as transitional assistance eligibility status, to offer lower negotiated prices to low-