

pharmacy. While it is possible that this requirement could represent some burden, we anticipate that the burden would be at most marginal. The pharmacy community routinely indicates that it is common practice for pharmacies to promote the use of generic drugs. Thus, this requirement is unlikely to represent a change in current practice for most pharmacies. The costs of the systems infrastructure required to furnish this pricing information will be borne by endorsed sponsors. The only cost to pharmacies would be the time involved in conveying the information to the beneficiary, which we anticipated would be small.

Pharmacies are also required upon request from the beneficiary to determine—either electronically or by telephone—how much of the beneficiary's transitional assistance dollars remain. The costs associated with this activity for pharmacies are expected to be small for several reasons. First, we anticipate that the costs associated with the development of the infrastructure for providing the balance of the transitional assistance dollars at the point of sale will be borne by endorsed sponsors, not network pharmacies. Second, we expect that the time involved in pharmacies determining the balance either electronically or by phone will be small. Finally, providing to beneficiaries the transitional assistance balance is not required to occur at the point of every sale, only at the beneficiary's request. Beneficiaries will have other options for accessing their card balances outside of the retail pharmacy, including through the endorsed sponsor's toll free line, which is likely to lessen the extent to which beneficiaries request balance determinations by pharmacies.

6. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This rule will not affect small rural hospitals since the program will be directed at outpatient prescription drugs, not drugs provided during a hospital stay. Prescription drugs provided during hospital stays are covered under Medicare as part of Medicare payments to hospitals. Therefore, we are not providing an analysis.

7. Alternatives Considered for, Especially, Small Pharmacies

In developing this program, we recognized that the statute already provided for a number of major program features that act to mitigate the potential effects of this program on retail pharmacies, including small pharmacies. First, we interpret the statute as reflecting Congressional intent that endorsed sponsors obtain manufacturer rebates, discounts, or other price concessions on some covered discount card drugs and that endorsed sponsors pass through some of these price concessions to enrollees in the form of lower prices. In addition, as discussed elsewhere in this rule, prices under this program will not be taken into account for the purposes of establishing "best price." Together, these program features relieve pressure from pharmacies, by ensuring that manufacturer rebates and discounts will be an important component of savings in this program and that endorsed sponsors will not rely solely on pharmacy discounts to compete for customers.

Second, the statute prohibits a mail order-only option. Mail order programs have some popularity and may be a convenient option for some beneficiaries. However, the prohibition of mail order only programs ensures that strong access to retail pharmacies will be an important feature of this program.

Finally, the program includes broad network access requirements that ensure that convenient access to retail pharmacies, including small pharmacies, will be a critical component of this program. Endorsed sponsors are required to have a pharmacy network of sufficient size to demonstrate that at least 90 percent of beneficiaries in urban areas served by the program live within 2 miles of a network pharmacy, at least 90 percent of beneficiaries in suburban areas served by the program live within 5 miles of a network pharmacy, and at least 70 percent of beneficiaries in rural areas served by the program live within 15 miles of a network pharmacy. Given these network access requirements, coupled with the industry norm for broad pharmacy networks, and the prohibition of a mail order only option, we anticipate that a very large number of small pharmacies and drug stores will be included in the networks of endorsed sponsors.

In addition to these statutory-related features of the program that mitigate its potential effects on pharmacies, we considered whether or not to require that endorsed sponsors negotiate

discounts on all drugs. We decided to only require that endorsed sponsors offer a discount on at least one drug in the therapeutic categories representing the drugs most commonly needed by beneficiaries. Since endorsed sponsors are less likely to negotiate manufacturer discounts on every drug dispensed, we believe our decision not to require discounts on every drug relieves pressure on pharmacies to provide discounts.

I. Estimated Administrative Costs and Anticipated Revenues of Endorsed Card Sponsors

1. Introduction

The statutory requirement that this program be provided by private, endorsed card sponsors places program success in providing savings and transitional assistance to Medicare beneficiaries on the participation of potential card sponsors. In light of this, we estimated the administrative costs and revenues faced by potential card sponsors to assess the willingness of private organizations to participate in the Medicare prescription drug discount card program. There are several incentives for organizations with pharmacy benefit management experience to choose to participate as endorsed card sponsors. We know that Medicare beneficiaries trust the Medicare name and are more confident about product offerings when they are Medicare approved or backed by the Medicare name. Receiving a Medicare endorsement will give potential card sponsors credibility with Medicare beneficiaries. In light of this, we believe that Medicare's endorsement of a discount program, and especially the availability of transitional assistance, will result in much greater enrollment with these organizations than the same entities might achieve if they decided to offer a discount program on their own. Greater enrollment means revenue from enrollment fees and more lives with which to negotiate manufacturer rebates. In addition, participation in the Medicare prescription drug discount card program may offer organizations the opportunity to gain experience working with Medicare beneficiaries and contracting with CMS prior to implementation of Medicare Part D.

The following cost and benefit analysis reflects the estimated major administrative costs and benefits incurred by an endorsed sponsor to implement the Medicare prescription drug discount card program. The administrative costs include start-up and program implementation activities, the production and distribution of