

demonstrates that insurance companies, pharmaceutical benefit managers, and others such as health maintenance organizations (HMOs) have been able to enter into arrangements similar to those in this program involving the participation of large and small pharmacy and drug store firms. These arrangements have resulted in lower prescription drug prices being made available to consumers who have insurance coverage for prescription drugs. There is evidence that both large and small pharmacies and drug stores participate in these arrangements with pharmaceutical benefit managers, and that pharmaceutical benefit managers are able to offer (employer) clients pharmacy networks containing the majority of retail pharmacy outlets. In addition, many pharmacies, including small pharmacies, offer senior discounts, and doing so in the context of this Medicare program may not be significantly different than current practice for some pharmacies.

The role of individual pharmacies, including small pharmacies, in this program is a critical one: they will be an integral part of the pharmacy networks of endorsed discount card programs, serving Medicare beneficiaries at the point of retail sale. The objectives of the program and the related design requirements will preclude an individual pharmacy or drug store from operating the full scale of contemplated activities that will be necessary to obtain an endorsement. Individual pharmacies could participate in the program by voluntarily entering into a drug card program's network with other pharmacies. Individual pharmacies are not in a market position to meet the requirements for endorsement, including the ability to serve a large number of enrollees and to garner manufacturer rebates. Retail pharmacy chains could possibly be organized to meet the requirements of Medicare endorsement explained elsewhere in this rule because of their size, type of experience and infrastructure.

Convenient access to retail pharmacies, regardless of size or ownership, by Medicare beneficiaries will be an important feature of the program. As discussed elsewhere in this rule, a discount card sponsor will have to have a contracted pharmacy network of sufficient size to demonstrate that at least 90 percent of Medicare beneficiaries in urban areas served by the program live within 2 miles of a contracted pharmacy (90/2), at least 90 percent of Medicare beneficiaries in suburban areas served by the program live within 5 miles of a contracted pharmacy (90/5), and at least 70 percent

of Medicare beneficiaries in rural areas served by the program live within 15 miles of a contracted pharmacy (70/15). These access ratio requirements, which are based on the Department of Defense TRICARE Retail Pharmacy (TRRx) program, are similar to the access standards in many commercial insured products and we believe they will require endorsed sponsors to support an extremely broad network of retail pharmacies.

Given the access ratio requirements and the provision that endorsed programs will not be allowed to offer a mail order only option, we believe that most pharmacies and drug stores (both chain and independent) will be invited and encouraged to participate in endorsed programs' networks, particularly small pharmacies in rural areas. This is generally the case in the current insured market and the TRRx program, and we do not anticipate significantly narrower networks in the endorsed programs. There are over 55,000 retail pharmacies in the United States. According to a report prepared for us by PricewaterhouseCoopers (PWC) ("Study of the Pharmaceutical Benefit Management Industry," June 2001), pharmacy benefit managers (PBMs) offer, as a general practice, standard national pharmacy networks, with 42,000 pharmacies in the typical network. Similarly, the Department of Defense reports that the TRRx program has more than 40,000 pharmacies in its network (as of June 2003). Furthermore, the PWC study reports that one leading PBM has 50,000 pharmacies in its more restricted network. Also, according to PWC, two large national PBMs have 98 percent of all pharmacies in the United States in their standard networks.

The inclusive access standard required for Medicare endorsement, coupled with the industry norm for broad pharmacy networks, lead us to believe that a very large number of small pharmacies and drug stores will be included in the networks of endorsed discount card programs. Further, we believe that small entities in rural areas especially will be included in order to meet the rural 70/15 standard for endorsement.

1. Estimated Impact on Small Entities

HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent. To assess whether the Medicare prescription drug discount card program meets these HHS criteria, we estimated the number of small entities affected and the average percentage impact on revenues. We also conducted a

sensitivity analysis to estimate the impact on revenues for pharmacies with a higher than average rate of customer participation in the Medicare prescription drug discount card program. These analyses found that while the program is expected to have some impact on a substantial number of small entities, it is not expected to have a significant economic impact. Based on these analyses, we certify that the Medicare prescription drug discount card program does not have a significant economic impact on a substantial number of small entities.

As a result, even if the RFA applied to this rule (which as discussed previously, we believe it does not) we would still not be required to perform a regulatory flexibility analysis. Nevertheless, due to the possibility that concerns may be voiced by some about the potential effects of the rule on small businesses, we have included in this section or in other sections of this document the various issues that are to be included in a regulatory flexibility analysis. To avoid repetition, we have not duplicated each of them here. In preceding sections of this document, we have included a description of the program and its objectives. In this and subsequent sections of this document, we include an estimate of the number of small entities affected; an estimate of the economic impact on small pharmacies including a sensitivity analysis assessing the potential for differential distributional effects on small pharmacies; a discussion of reporting, recordkeeping, and other compliance requirements; and a description of the alternatives considered to minimize the economic impact on small pharmacies.

2. Number of Small Entities Affected

For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. The Small Business Administration (SBA), on its Web site (<http://www.sba.gov/size/naicstb2-ret.html>), provides a size standard for pharmacies and drug stores (NAICS code 446110 or SIC code 5912) of revenues of \$6 million or less annually for the purpose of determining whether entities are small businesses. The revenue standard for small pharmacies and drug stores was recently increased from \$5 million to \$6 million in February 2002 to account for inflation.

To assess the number of small entities affected by this program, and the amount of revenue involved for these