

will not require that these arrangements be finalized and approved by us within 6 months after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

As permitted under section 1860D–31(j)(1) of the Act, we will allow applicants seeking special endorsement in the territories to request that we waive application of one or more of the other requirements of the Medicare drug discount card program. In its application the applicant must cite the statutory or regulatory provision(s) it wishes us to waive, and explain why: (1) Such waiver is necessary to enable the applicant to either initiate enrollment activities in the territories within six months of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 or accommodate the unique needs of pharmacies in the territories; or (2) compliance with the requirement(s) in question would be impracticable or inefficient. Applicants also must provide an assessment of the impact of waiving the requirement(s) in question on beneficiaries residing in the territories. If we grant the waiver, we will waive the applicable requirement(s) for all similarly situated applicants seeking special endorsement.

We will provide technical assistance to applicants seeking to offer endorsed programs in the territories, including holding a special break-out session at the pre-application conference. In addition, as additional incentives to encourage applicants to offer endorsed programs in the territories, we will, to the extent possible, provide expedited marketing review of special endorsed sponsors' information and outreach materials, and provide special recognition for these sponsors on the Medicare drug discount card Web site.

Applicants should note that special endorsed sponsors in the territories will not be asked to administer transitional assistance on behalf of CMS; rather, transitional assistance provided to residents in the territories will be a separate program independently operated by each territory, as described below.

3. Transitional Assistance

Section 1860D–31(j)(2)(A) of the Act provides that a territory may provide transitional assistance to some or all individuals residing in the territory who are entitled to benefits under part A or enrolled under part B with incomes no more than 135 percent of the poverty line for their family size, regardless of whether the individual receives an outpatient drug benefit under Medicaid

or any other coverage sources (such as FEHBP, Tricare, or employer-sponsored health insurance). In accordance with section 1860D–31(j)(2)(B) of the Act, a territory wishing to provide transitional assistance to eligible beneficiaries must submit to CMS for our approval a plan describing its proposed transitional assistance program, including:

- The territory's criteria and process for determining beneficiaries' eligibility for transitional assistance (including its definition of income and family size) for individuals who reside in the territories, who are entitled to benefits under Medicare Part A or enrolled under Medicare Part B, and who have income at or below 135 percent of the poverty line for the contiguous United States; and
- The process for ensuring that allotment provided to the territory under section 1860D–31(j)(2) of the Act will be used only to provide covered discount card drugs to those individuals determined eligible for transitional assistance; and
- The territory's assurance that it will operate its transitional assistance plan as approved.

Section 1860D–31(j)(2)(C) of the Act provides that territories with approved transitional assistance plans will receive in the aggregate \$35 million for the duration of the Medicare drug discount card program, which will be allocated among such territories in the manner described below. Territories must submit their plans to CMS within 90 days of the publication of this rule so as to allow us adequate time to review and approve their plans and determine each territory's allocated share of the \$35 million.

CMS may request reports or information to substantiate that the territories have administered the program consistent with the territory's approved transitional assistance plan.

Section 1860D–31(j)(2)(D) of the Act provides that the Secretary shall calculate the portion of the \$35 million allocated to a territory with an approved plan for transitional assistance by multiplying \$35,000,000 by the ratio of—

(1) The number of individuals who are entitled to benefits under part A or enrolled under part B and who reside in the territory (as determined by the Secretary as of July 1, 2003), to

(2) The sum of such number for all territories with an approved plan under this program.

Section 1860D–31(j)(2)(D) provides that amounts made available to a territory for transitional assistance which are not used to provide transitional assistance will be added to

the amount available to that territory for purposes of carrying out the Medicare Part D drug benefit.

K. Special Rules and Part B Premium and Appropriations

1860D–31(k)(2)(B) states that amounts payable from the Transitional Assistance Account shall not be taken into account in computing the actuarial rates or premium amounts under section 1839 of the Act. Similarly, section 105(a) amends section 1839(g) of the Act by ensuring that any estimations used to calculate the Part B monthly premium rate shall exclude estimates attributable to the Medicare prescription drug discount card and transitional assistance program under section 1860D–31 of the Act. We have accordingly made changes to the regulations in 42 CFR 408.20 to reflect these statutory provisions.

IV. Regulatory Impact Analysis and Regulatory Flexibility Act Analysis

A. Overall Impact

We have examined the impacts of this rule under Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually). While the ultimate impact of this program will depend upon the final designs of endorsed discount card sponsors' programs, our estimate is that this rule is economically significant as measured by the \$100 million standard. The savings to beneficiaries from discount card activities, including negotiated prices on prescription drugs and education about generic substitution by endorsed sponsors, will represent an economic impact ranging from \$1.4 billion to \$1.8 billion in the last nine months of 2004 (assuming for the purposes of this impact analysis implementation beginning second quarter 2004), \$2.0 billion to \$2.7 billion in 2005, and \$0.4 billion to \$0.6 billion in the first four and one-half months of 2006. This impact would not affect the