

The burden associated with this requirement is the time and effort for the individual to submit a new election form. While this section is subject to the PRA, this burden is currently captured in approved collection 0938-0753.

Section 422.74(d)(4)(i)—In the final rule, this section states that unless continuation of enrollment is elected under § 422.54, the M+C organization must disenroll an individual if the M+C organization establishes, on the basis of a written statement from the individual or other evidence acceptable to us, that the individual has permanently moved.

This section requires that the individual must prepare and provide a written statement to the M+C organization that he or she has permanently moved. While this requirement is subject to the PRA, the burden associated with this requirement is captured in approved collection 0938-0753.

Section 422.106(c)(1)—M+C organizations may request, in writing, a waiver or modification of those requirements in part 422 that hinder the design of, the offering of, or the enrollment in, M+C plans under contracts between M+C organizations and employers, labor organizations, or the trustees of benefits funds.

We believe that the burden associated with this requirement is minimal. We anticipate approximately 100 requests for waivers or modifications submitted on an annual basis and that it will take approximately 2 hours to prepare each request. The total annual burden associated with this requirement is estimated to be 200 hours.

Section 422.106(c)(2)—In this final rule, this section states that approved waivers or modifications under this paragraph may be used by any M+C organization on developing its ACR proposal. Any M+C organization using a waiver or modification must include that information in the cover letter of its ACR proposal submission.

The burden associated with this requirement is the time and effort for the M+C organization to include the information in the cover letter of its ACR proposal submission. Although this requirement is subject to the PRA, the burden is minimal; therefore, the burden is captured in the analysis for § 422.106(c)(1).

Section 422.111(f)(8)(iii)—In this final rule, this section has been revised to add any reduction in Part B premiums to the list of information that must be disclosed to each enrollee electing an M+C plan.

The burden associated with this requirement is the time and effort for the M+C organization to disclose

information to each enrollee electing an M+C plan. Although this requirement is subject to the PRA, the burden associated with this requirement is captured in approved collection 0938-0778.

Section 422.152(f)(4)—We have added this section to reflect the statutory provision of requiring M+C organizations' quality assurance programs to have a separate focus on racial and ethnic minorities. We estimate that it will take each M+C organization approximately 2 hours to add a separate focus on racial and ethnic minorities to its quality assurance program. Since there are approximately 150 M+C organizations, we estimate the annual burden associated with this requirement to be approximately 300 hours.

Section 422.210(a)(1)—In the final rule, this section states that each M+C organization must provide to us upon request, descriptive information about its physician incentive plan in sufficient detail to enable us to determine whether that plan complies with the requirements of § 422.208.

This section requires the M+C organization to prepare and submit, upon request, descriptive information to us. While this requirement is subject to the PRA, the burden associated with this requirement is captured in approved collection 0938-0700.

Section 422.266(a)—In this final rule, an M+C organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under § 418.24 of this chapter about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the M+C organization or a related entity).

While this requirement is subject to the PRA, the burden associated with it is captured in approved collection 0938-0753.

In summary, the total burden hours for this proposed rule is calculated to be 500 hours. The breakdown is as follows:

§ 417.479(h)—burden captured in 0938-0700

§ 422.50(a)(2)—burden captured in 0938-0753

§ 422.74(d)(4)(i)—burden captured in 0938-0753

§ 422.106(c)(1)—200 hours

§ 422.106(c)(2)—burden captured in 422.106(c)(1)

§ 422.111(f)(8)(iii)—burden captured in 0938-0753

§ 422.152(f)(4)—300 hours

§ 422.210(a)(1)—burden captured in 0938-0700

§ 422.266(a)—burden captured in 0938-0753

0938-0700 is approved for 450 hours and expires on April 30, 2004 and 0938-0753 is approved for 2,120,006 hours and expires on October 31, 2005.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354). 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).

This final rule, which changes M+C regulations in accordance with provisions set forth in the BIPA, is not a major rule with economically significant effects as defined in Title 5, U.S.C. section 804(2) and is not an economically significant rule under Executive Order 12866. This final rule will result in increases in total expenditures of less than \$100 million per year.

The budgetary impact of section 605 of the BIPA, which mandated revised ESRD payments, was estimated to be \$270 million over the 5 years between FY 2002 to FY 2006, based on the FY 2002 President's budget. These payments are in the current baseline and have no impact on the budget. In addition, these provisions have already been implemented through our 2002 annual payment notice. The additional cash expenditures for these M+C ESRD beneficiaries under this provision of the BIPA affected those M+C organizations that enrolled the approximately 18,000 ESRD beneficiaries in their plans. Additional expenditures for this provision have been incorporated into the M+C payment rates from CY 2002 forward.

This estimate assumed continuation of the current restrictions on enrollment in the M+C program for ESRD beneficiaries. This estimate also included the impact of adjusting for age and sex and the impact of raising the ESRD base rates by 3 percent. We estimate that the change in policy for