

are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. For purposes of the RFA, all of the 16 not-for-profit Medicare/Medicaid RNHCI providers are considered small businesses according to the Small Business Administration's size standards, with total revenues of \$6 million or less in any one year. Individuals and States are not included in the definition of a small entity.

Currently, only one religious group is participating in the RNHCI program and no other groups have applied for participation. The RNHCI are operated as independent facilities by individual boards composed of members from the religious group. The facilities are not in competition with other medical care providers in any geographical area since they pursue a religious rather than a medical approach to health care. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

2. Effects on Other Health Care Providers

In addition, 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 have a significant impact on small rural hospitals. The RNHCI are not in competition with other medical care providers in any geographical area, since they pursue a religious rather than a medical approach to health care. Currently, all of the RNHCI are located in metropolitan rather than rural areas. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

3. Effects on States, Local or Tribal Governments

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This rule will have no consequential effect on the

governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

In accordance with the provisions of Executive Order 13132, this regulation will not significantly affect any State or local government. This rule describes only processes that must be undertaken if a State chooses to exercise its option to amend the State plan and include coverage of inpatient RNHCI services.

Those States that have RNHCI facilities and have selected to offer the optional RNHCI service are very limited. Currently, we only have 16 facilities participating in Medicare and one of these is dually eligible to participate in Medicare and Medicaid. The monitoring of the program is conducted by staff in the Boston Regional Office (Region I) and they will be responsible for the survey and certification activity that is usually conducted by a State Agency. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

4. Effect on the Medicare and Medicaid Programs

Section 4454 of BBA '97 removed the authorization for payment for services furnished in Christian Science sanatoria from under both Medicare and Medicaid. Section 4454 authorizes payment for inpatient services in an RNHCI for beneficiaries who, for religious reasons, are conscientiously opposed to the acceptance of medical care. Section 4454 of BBA '97 provides for coverage of the nonmedical aspects of inpatient care services in RNHCI under Medicare and as a State option under Medicaid. In order for a provider to satisfy the definition of a religious nonmedical health care institution, for both Medicare and Medicaid, it must satisfy the 10 qualifying provisions contained in section 1861(ss)(1) of the Act. The RNHCI choosing to participate in Medicare must also be in compliance with both the conditions for coverage and the conditions of participation contained in the regulations. Neither Medicare nor Medicaid will pay for any religious aspects of care provided in these facilities. CMS has used one fiscal intermediary to handle all RNHCI and the Boston Regional Office to monitor the process, and we plan to continue that arrangement.

Section 4454 of BBA '97 establishes certain controls on the amount of expenditures for RNHCI services in a given FFY. Section 1821(c)(2)(C) of the Act explains the operation of these controls through the use of a trigger level.

The trigger level is used to determine if Medicare payments for the current FFY need to be adjusted. If the estimated level of expenditures for an FFY exceeds the trigger level for that FFY, we are required under statute to make a proportional adjustment to payments or alternative adjustments to prevent expenditures from exceeding the trigger level.

BBA '97 precludes administrative or judicial review of adjustments that we determine are necessary to control expenditures. The trigger level is also used to activate the sunset provision, which prohibits us from accepting any new elections when estimated expenditures exceed the trigger level for 3 consecutive fiscal years. It must be noted that the trigger level has not been even closely approached since the inception of the program.

Currently, there are 16 RNHCI that are furnishing services and receiving payment under Medicare. One of these facilities is dually eligible to participate in Medicare and Medicaid. There have been no Medicaid expenditure reports submitted by any State for several years.

5. Effects on RNHCI

The rule enables RNHCI providers and beneficiaries the opportunity to continue to receive funding for inpatient health care service that are in keeping with their religious convictions. Additionally, the rule provides that a beneficiary will always have the option of choosing to seek conventional medical care for covered services.

C. Alternatives Considered

This final rule adheres to the statutory provisions, which in many instances were very prescriptive; however, we used every opportunity possible to consider alternative approaches as discussed below.

Elections

The statute does not prescribe when the election must be made except to specify that it must be made before receiving care. Initially, we considered the possibility of opening the election process to all eligible beneficiaries, who would wish to pursue RNHCI services, to ensure these benefits would be available when they were admitted to an RNHCI. However, some religious groups consider it acceptable to receive some medical care (for example, closed