

address, and policy challenged) and collect and photocopy scientific and clinical evidence. It should actually take less than that amount of time in NCD challenges, since the aggrieved party has already sent us the information and merely has to send it again.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn.: Dawn Willingham, Attn: CMS-3063-F, Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), as amended by Executive Order 13258, and the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), as amended. 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). Based on provider, beneficiary, and Agency costs, our analysis indicates that the costs involved with the implementation of this rule will not exceed \$100 million annually. Therefore, this rule is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less annually. Individuals and States are not included in the definition of a small entity.

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 603 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.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

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 expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. We do not believe that this rule would have an effect on the governments mentioned, nor would the private sector costs associated with the rule be greater than \$110 million.

B. Federalism

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. This final rule will not have a substantial effect on State or local governments.

C. Anticipated Effects

1. Effects on Medicare Beneficiaries

In developing this rule, we considered how to make it user-friendly for the individual beneficiaries who qualify as aggrieved parties to initiate the review of an LCD or an NCD. Possible access obstacles for some aggrieved parties include limited financial resources, limited mobility, various disabilities, absence of legal representation, and difficulty in compiling and presenting scientific and clinical materials. We have sought to include means to alleviate these obstacles as much as possible through this rule, but would also expect the ALJs and the Board to use the flexibility in this rule to respond to obstacles that may confront

individual aggrieved parties in particular cases.

Some concerns may remain about how to facilitate participation, especially when evidence is taken in person, by aggrieved parties with limited mobility or resources. This final rule seeks to address this by providing for most evidence to be submitted in written form and by allowing use of a variety of electronic means for remote attendance at any oral proceeding, if one is needed. In addition, the rule provides flexibility for ALJs and the Board to tailor proceedings in each case to best reflect the needs of the parties, the appropriate scope of participation, and the nature of the issues presented.

While we require some documentation to support a complainant's assertions of being an aggrieved party (*see* § 426.400 and § 426.500), we will accept that documentation as sufficient to show standing to challenge an LCD or an NCD. By limiting this documentation, we seek to simplify the process for the beneficiary, to alleviate privacy concerns about confidential medical records and other patient-specific information, and to reduce any intrusive discovery burden on beneficiaries.

Our intent is to ensure that beneficiaries fully understand these rights. When this final rule is published, we expect to produce a user-friendly guide that beneficiaries may use to assist them in accessing this process.

We have also provided for appropriate measures to be taken to address confidentiality and privilege issues relating to privileged or confidential trade secrets, commercial information, or financial information.

2. Effects on Providers

We do not believe that the provisions of this rule will have a significant effect on providers, since the Congress developed the BIPA 522 process for beneficiaries. Providers may be requested, however, to supply documentation that an aggrieved party is in need of a specific service, and to assist in representing an aggrieved party. In addition, we have clarified in the final rule that this document may be in the form of an order or other existing language from the beneficiary's medical record and need not be newly created material. It is also possible for a provider to be subpoenaed under § 426.435 and § 426.535, but § 426.445 and § 426.545 will allow for compensation under this circumstance. While there may be time requirements placed on providers and expert witnesses in this respect, there will be no additional monetary expenses. As a