

- Adherence to approved program management and MIP budgets.
- Control of administrative cost and benefit payments.

E. Administrative Activities

We may measure a DMEPOS regional carrier's administrative ability to manage the Medicare program. We may evaluate the efficiency and effectiveness of its operations, its system of internal controls, and its compliance with our directives and initiatives. Our evaluation of a DMEPOS regional carrier under this criterion may include, but is not limited to review of the following:

- Systems Security.
- Disaster recovery plan.
- Internal controls establishment and use, including the degree to which the contractor cooperates with the Secretary in complying with the FMFIA.

VIII. Action Based on Performance Evaluations

We evaluate a contractor's performance against applicable program requirements for each criterion. Each contractor must certify that all information submitted to us relating to the contract management process, including, without limitation, all files, records, documents and data, whether in written, electronic, or other form, is accurate and complete to the best of the contractor's knowledge and belief. A contractor will also be required to certify that its files, records, documents, and data have not been manipulated or falsified in an effort to receive a more favorable performance evaluation. A contractor must further certify that, to the best of its knowledge and belief, the contractor has submitted, without withholding any relevant information, all information required to be submitted with respect to the contract management process under the authority of applicable law(s), regulation(s), contract(s), or our manual provision(s). Any contractor that makes a false, fictitious, or fraudulent certification may be subject to criminal and/or civil prosecution, as well as appropriate administrative action. This administrative action may include debarment or suspension of the contractor, as well as the termination or nonrenewal of a contract.

If a contractor meets the level of performance required by operational instructions, it meets the requirements of that criterion. When we determine a contractor is not meeting performance requirements, we will use the terms "major nonconformance" or "minor nonconformance" to classify our findings. A major nonconformance is a nonconformance that is likely to result

in failure of the supplies or services, or to materially reduce the usability of the supplies or services for their intended purpose. A minor nonconformance is a nonconformance that is not likely to materially reduce the usability of the supplies or services for their intended purpose, or is a departure from established standards having little bearing on the effective use or operation of the supplies or services. The contractor will be required to develop and implement a PIP for findings determined to be either a major or minor nonconformance. The contractor will be monitored to ensure effective and efficient compliance with the PIP, and to ensure improved performance when requirements are not met.

The results of performance evaluations and assessments under all criteria applying to intermediaries, carriers, RHHIs, and DMEPOS regional carriers will be used for contract management activities and will be published in the contractor's annual Report of Contractor Performance (RCP). We may initiate administrative actions as a result of the evaluation of contractor performance based on these performance criteria. Under sections 1816 and 1842 of the Act, we consider the results of the evaluation in our determinations when—

- Entering into, renewing, or terminating agreements or contracts with contractors, and
- Deciding other contract actions for intermediaries and carriers (such as deletion of an automatic renewal clause). These decisions are made on a case-by-case basis and depend primarily on the nature and degree of performance. More specifically, these decisions depend on the following:
 - Relative overall performance compared to other contractors.
 - Number of criteria in which nonconformance occurs.
 - Extent of each nonconformance.
 - Relative significance of the requirement for which nonconformance occurs within the overall evaluation program.
 - Efforts to improve program quality, service, and efficiency.
 - Deciding the assignment or reassignment of providers and designation of regional or national intermediaries for classes of providers.

We make individual contract action decisions after considering these factors in terms of their relative significance and impact on the effective and efficient administration of the Medicare program.

In addition, if the cost incurred by the intermediary, RHHI, carrier, or DMEPOS

regional carrier to meet its contractual requirements exceeds the amount that we find to be reasonable and adequate to meet the cost that must be incurred by an efficiently and economically operated intermediary or carrier, these high costs may also be grounds for adverse action.

IX. Regulatory Impact Statement

We have examined the impacts of this notice as required by 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 in any one year). Since this notice only describes criteria and standards for evaluating FIs (including RHHIs), carriers, and DMEPOS regional carriers and has no significant economic impact on the program, its beneficiaries, providers or suppliers, this is not a major notice.

The RFA requires agencies to analyze options for regulatory relief of small businesses. This notice does not affect small businesses; individuals and States are not included in the definition of small business entities.

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 notice does not affect 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 expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. In accordance with Section 202, we have determined that the notice does not impose any unfunded mandates on State, local or tribal governments, or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a notice that imposes substantial direct