

## B. Regulatory Impact Analysis

### *Executive Order 12866 Statement*

Under Executive Order 12866, the Department must determine whether a regulatory action is "significant" and therefore subject to the requirements of the Executive Order and subject to review by the Office of Management and Budget (OMB). Under section 3(f) of the Executive Order, a "significant regulatory action" is an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. On the basis of these criteria, it has been determined that this regulatory action is significant under section 3(f)(4) of the Executive Order. Accordingly, OMB has reviewed this regulation.

### *Paperwork Reduction Act*

The rule being issued here is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) because it does not contain a "collection of information" as defined in 44 U.S.C. 3502(3).

### *Regulatory Flexibility Act*

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires each Federal agency to perform a regulatory flexibility analysis for all rules subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) unless the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. Small entities include small businesses, organizations, and governmental jurisdictions.

Because these rules were issued as interim final rules and not as a notice of proposed rulemaking, the RFA does not apply and the Department is not required to either certify that the rule will not have a significant economic impact on a substantial number of small entities, or conduct a regulatory

flexibility analysis. The Department does not anticipate that this final rule will impose a significant impact on a substantial number of small entities, however, regardless of whether one uses the definition of small entity found in regulations issued by the Small Business Administration (13 CFR § 121.201) or one defines small entity, on the basis of section 104(a)(2) of ERISA, as an employee benefit plan with fewer than 100 participants.

### *Small Business Regulatory Enforcement Fairness Act*

The final rule being issued here is subject to the provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to Congress and the Comptroller General for review. The rule is not a "major rule" as that term is defined in 5 U.S.C. 804, because it is not likely to result in (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

### *Unfunded Mandates Reform Act*

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), as well as Executive Order 12875, this final rule does not include any Federal mandate that may result in expenditures by State, local, or tribal governments, and will not impose an annual burden of \$100 million or more on the private sector.

### *Federalism Statement Under Executive Order 13132*

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have substantial direct effects on the states, the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe in the preamble to the regulation the extent of their consultation and the nature of the

concerns of state and local officials, as well as the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of state and local officials have been met.

In the Department's view, these final regulations do not have federalism implications because they do not have substantial direct effects on the states, the relationship between the national government and the states, or on the distribution of power and responsibilities among various levels of government. Not only do these regulations not reduce state discretion, the reports they require will facilitate state enforcement of their own laws as they apply to MEWAs since the reports will be available to the states and will identify MEWAs operating in each state.

Although the Department concludes that these final regulations do not have federalism implications, in keeping with the spirit of the Executive Order that agencies shall closely examine any policies that may have federalism implications or limit the policy making discretion of the states, the Department of Labor engages in extensive efforts to consult with and work cooperatively with affected state and local officials.

For example, the Department attends quarterly meetings of the National Association of Insurance Commissioners (NAIC) to listen to the concerns of state insurance departments. The NAIC is a non-profit corporation established by the insurance commissioners in the 50 states, the District of Columbia, and the four U.S. territories that, among other things, provides a forum for the development of uniform policy when uniformity is appropriate. Its members meet, discuss, and offer solutions to mutual problems. The NAIC sponsors quarterly meetings to provide a forum for the exchange of ideas, and in-depth consideration of insurance issues by regulators, industry representatives, and consumers. In addition to the general discussions, committee meetings, and task force meetings, the NAIC sponsors standing HIPAA meetings for members during the quarterly conferences, including a Centers for Medicare and Medicaid Services (CMS)/Department of Labor (DOL) meeting on HIPAA issues. (This meeting provides CMS and DOL the opportunity to provide updates on regulations, bulletins, enforcement actions, and outreach efforts regarding HIPAA.) In these quarterly meetings, issues relating to MEWAs and the implementation of the Form M-1 filing requirement are frequently discussed and, periodically, entire sessions are scheduled that are dedicated exclusively to MEWA/Form M-1 issues.