

thus this section refers to the "ALJ decision" rather than to an "initial decision." Neither section 1320a-7a nor the APA requires a second level of administrative review, although this is generally available in Department hearings. We anticipate addressing the issue of further administrative review in the notice-and-comment rulemaking that we plan for the remainder of the Enforcement Rule.

Judicial Review; Stay of ALJ Decision

Section 160.568 provides for judicial review of penalties imposed under this part, as authorized by 42 U.S.C. 1320a-7a(e). Section 160.570 provides that a respondent may request a stay of the effective date of a penalty pending judicial review. This section tracks § 1005.22(b) of the OIG regulations.

IV. Impact Statement and Other Required Analyses

Paperwork Reduction Act

We reviewed this interim final rule to determine whether it invokes issues that would subject it to the Paperwork Reduction Act (PRA). While the PRA applies to agencies and collections of information conducted or sponsored by those agencies, 5 CFR 1320.4(a) exempts collections of information that occur "during the conduct of . . . an administrative action, investigation, or audit involving an agency against specific individuals or entities," except for investigations or audits "undertaken with reference to a category of individual or entities such as a class of licensees or an entire industry." The rules adopted below come squarely within this exemption, as they deal entirely with administrative investigations and actions against specific individuals or entities. Therefore, we have determined that the PRA does not apply to this rule.

Executive Order 12866; Unfunded Mandates Reform Act of 1995; Regulatory Flexibility Act; Small Business Regulatory Enforcement Fairness Act of 1996; Executive Order 13132

We have examined the impacts of this rule as required by E.O. 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 E.O. 13132.

E.O. 12866 (as amended by E.O. 13258, which merely reassigns responsibility of duties) 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 in any 1 year). HHS has concluded that this rule should be treated as a "significant regulatory action" within the meaning of section 3(f)(4) of E.O. 12866 because the HIPAA provisions to be enforced have extremely broad implications for the nation's health care system, and because of the novel issues presented by, and the uncertainties surrounding, compliance among covered entities. However, E.O. 12866 requires a full economic impact analysis only for "economically significant" rules, which are defined in section 3(f)(1) of the order as rules that may "have an annual effect on the economy of \$100 million or more, or adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." Because this rule is procedural in nature, it has no intrinsic significant economic impact; therefore, no economic impact analysis has been prepared.

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 \$6 million in any 1 year. This interim final rule is purely procedural in nature and, as such, HHS has determined that this regulation will not have a significant economic impact on a substantial number of small entities. The regulation simply implements procedures necessitated by enactment of HIPAA, in order to allow the Secretary to enforce subtitle F of Title II of HIPAA.

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 (proposed documents)/604 (final documents) 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 rule implements procedures necessary for the Secretary to enforce subtitle F of Title II of HIPAA.

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 \$100 million. Because this rule is procedural in nature, it will not impose a burden large enough to require a section 202 statement under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*).

E.O. 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 interim final rule does not have "Federalism implications." The rule does not have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government" and therefore is not subject to E.O. 13132 (Federalism).

The Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) requires that rules that will have an impact on the economy of \$100 million or more per annum be submitted for Congressional review. Because this rule is procedural in nature, it will not impose a burden large enough to require Congressional review under the statute.

List of Subjects in 45 CFR Part 160

Administrative practice and procedure, Computer technology, Healthcare, Health facilities, Health insurance, Health records, Hospitals, Investigations, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter C, part 160 as set forth below.

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 160 is revised to read as follows:

Authority: 42 U.S.C. 1302(a), 42 U.S.C. 1320d—1320d-8, and sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2(*note*)).