

title III of Pub. L. 99-660 (42 U.S.C. 300aa-note) and section 2114(c) of the Public Health Service Act (42 U.S.C. 300aa-14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program."

Second, we are revising § 100.3(c), entitled "Effective date provisions," to change the term "United States Claims Court" wherever it appears to read "United States Court of Federal Claims", in accordance with section 902(b) of title IX, Pub. L. 102-572, the Federal Courts Administration Act of 1992 (See 106 Stat. 4516).

In addition, the Department is making a technical change to the existing regulations (42 CFR part 100) by revising the currently codified acronym used to refer to the National Vaccine Injury Compensation Program from "NVIC" to "VICP" wherever it appears under part 100. "VICP" has been used for the entire history of the program to avoid confusion with the parents' advocacy group known as the National Vaccine Information Center (NVIC), Dissatisfied Parents Together (DPT).

Since these changes are of a technical nature, the Secretary has determined pursuant to 5 U.S.C. 553 and departmental policy that it is unnecessary and impractical to follow proposed rulemaking procedures.

Economic Impact

The NPRM preamble erred in not explaining that this rule will not have a significant impact on a substantial number of small businesses because it will have only small effects, and those primarily on individuals. Attorneys, while small entities within the meaning of the Act, will still be awarded costs and fees for cases they bring on a reasonable basis. The reduced number of vaccine cases brought will be negligible measured against overall business opportunities for lawyers. Therefore, SBA is incorrect in saying that a regulatory flexibility analysis is required. Therefore, the Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet

certain standards, such as avoiding unnecessary burden. Regulations which are "significant" because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues, require special analysis.

As stated above, this final regulation modifies the Vaccine Injury Table based on legal authority, and under that authority the Court will award such fees and costs as appropriate under the law. As such, the regulation would have little direct effect on the economy or on Federal or State expenditures. For the same reasons, the Secretary has also determined that this is not a "significant" rule under Executive Order 12866.

Effect of the New Rule

The NPRM failed to explain the effect of the rule for individuals who were not eligible to file petitions based on the original Vaccine Injury Table, but who may be eligible to file petitions based on the revised Table. The Act permits such individuals to file a petition for such compensation not later than 2 years after the effective date of the revision if the injury or death occurred no more than 8 years before the effective date of the revision of the Table. See 42 U.S.C. 300aa-16(b). As part of the Omnibus Reconciliation Act of 1993, Congress amended this section to permit individuals to file claims within this 2-year period, even if they had already filed a claim involving a particular vaccine, but only if the Table revision will "significantly increase the likelihood of obtaining compensation." See Pub. L. 103-66, sec. 13632(a)(1). (August 10, 1993). For example, this amendment would permit an individual whose claim alleging vaccine-related arthritis had been dismissed by the Claims Court to file a new claim for the same vaccine-related injury, if the individual can show that the addition of arthritis to the Table as a rubella vaccine-related condition has significantly increased the likelihood of obtaining compensation. The Department believes that the amendment would not permit someone who had had a claim for an alleged vaccine-related encephalopathy subsequent to DTP vaccine to refile a claim that had been dismissed by the Claims Court, as the changes in the Table related to DTP and encephalopathy do not appear to significantly increase the likelihood of obtaining compensation.

Possible Effect on Other Legislation

This rule will not have an effect on the Vaccines for Children Program,

implemented by the Centers for Disease Control and Prevention under section 1928 of the Social Security Act, as enacted by section 13631 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103-66, August 10, 1993). This section provides for the establishment of a program to distribute free vaccines to all vaccine-eligible children, as defined by this section. The final rule modifies the existing Vaccine Injury Table, a mechanism by which compensation is awarded to individuals who have been found to have suffered from vaccine-related injuries. Because the two authorities are not related, the publication of this rule should not have any impact on the Vaccines for Children Program.

Paperwork Reduction Act of 1980

This final rule has no information collection requirements.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, Immunization.

Dated: November 16, 1993.

Philip R. Lee,

Assistant Secretary for Health.

Approved: November 9, 1994.

Donna E. Shalala,

Secretary.

Accordingly, 42 CFR part 100 is amended as set forth below.

PART 100—VACCINE INJURY COMPENSATION

1. The authority citation for part 100 is revised to read as follows:

Authority: Sec. 215 of the Public Health Service Act (42 U.S.C. 216); sec. 2115 of the PHS Act, 100 Stat. 3767, as amended (42 U.S.C. 300aa-15); § 100.3, the Vaccine Injury Table, issued under sec. 312 of Pub. L. 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and sec. 2114(c) of the PHS Act (42 U.S.C. 300aa-14(c)).

2. Section 100.1 is revised to read as follows:

§ 100.1 Applicability.

This part applies to the National Vaccine Injury Compensation Program (VICP) under subtitle 2 of title XXI of the Public Health Service (PHS) Act.

3. The first sentence in § 100.2 is revised to read as follows:

§ 100.2 Average cost of a health insurance policy.

For purposes of determining the amount of compensation under the VICP, section 2115(a)(3)(B) of the PHS Act, 42 U.S.C. 300aa.15(a)(3)(B), provides that certain individuals are entitled to receive an amount reflecting