DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 100

RIN 0905–AD64

National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table

AGENCY: Health Resources and Services Administration, PHS, HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the existing regulations governing the National Vaccine Injury Compensation Program (VICP) by adding a new section regarding the Vaccine Injury Table (Table) to the regulations, pursuant to section 312 of the National Childhood Vaccine Injury Act of 1986 and section 2114(c) of the Public Health Service Act (the Act). The VICP provides a system of no-fault compensation for certain individuals who have been injured by specific childhood vaccines. The Vaccine Injury Table included in the Act establishes presumptions about causation of certain illnesses and conditions, which are used by the Court to adjudicate petitions. The amendments to the Vaccine Injury Table will affect only those petitions filed for compensation under the VICP after the effective date of this rule.

EFFECTIVE DATE: This regulation is effective March 10, 1995.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, M.D., Chief Medical Officer and Deputy Director, Division of Vaccine Injury Compensation, Bureau of Health Professions, (301) 443–4198, or David Benor, Senior Attorney, Office of the General Counsel, (301) 443–2006.

SUPPLEMENTARY INFORMATION:

Introduction and Procedural History

On August 14, 1992, the Assistant Secretary for Health, with the approval of the Secretary of Health and Human Services (the Secretary), published in the **Federal Register** (57 FR 36878) a Notice of Proposed Rulemaking (NPRM) to amend the Vaccine Injury Table (the Table). (A correction notice to the NPRM was also published on September 11, 1992, 57 FR 41809). The NPRM was issued pursuant to section 2114(c) of the Act, which authorizes the Secretary to promulgate regulations to modify the Table.

As stated in the preamble to the proposed rule, under section 312 of the National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660), Congress mandated that the Secretary review the scientific literature and other information on specific adverse consequences of pertussis and rubella vaccines. The Secretary entered into a contract with the Institute of Medicine (IOM), as recommended by Congress, to perform this review. The IOM published a report of its review entitled, ''Adverse Effects of Pertussis and Rubella Vaccines,'' on August 27, 1991 (hereinafter ''IOM Report''). The Public Health Service Task Force on the VICP evaluated the IOM report and made the initial recommendations regarding possible revision of the Table.

These recommendations were reviewed by a special subcommittee of the National Vaccine Advisory Committee (NVAC) (a committee authorized under section 2105 of the Act). The subcommittee overwhelmingly endorsed all of the proposed revisions except for the addition of chronic arthritis to the Table. The full NVAC endorsed the subcommittee's recommendations for revising the Table.

The Advisory Commission on Childhood Vaccines (ACCV), whose membership by statutory directive reflects a variety of views relating to childhood immunizations (authorized under section 2119 of the Act), considered the NVAC report as well as the PHS Task Force recommendations. The ACCV deliberations included public policy considerations, whereas the NVAC charge was to consider only the scientific issues raised by the existing Table, the recent IOM report, and other scientific information. The ACCV voted approval of all of the PHS Task Force recommendations except for the removal of the condition of Encephalopathy. The ACCV voted unanimously to retain Encephalopathy on the Table provided the existing definition in the Aids to Interpretation was clarified. The Secretary proposed changes to the Table after reviewing the recommendations of these three entities.

As provided by section 2114(c) of the Act, the Department provided for a 6-month comment period, which closed on February 11, 1993. On December 3, 1992, the Department held a public hearing for the purpose of receiving oral testimony on the proposed rule.

During the process of analyzing the comments received in response to the NPRM, the Agency became aware of the imminent publication of a 10-year follow-up study to the National Childhood Encephalopathy Study (NCES) (Madge N., Diamond J., Miller D., Ross E., McManus C., Wadsworth J., Yule W. The National Childhood Encephalopathy Study: A 10-year follow-up. A report of the medical, social, behavioural and educational outcomes after serious, acute, neurologic illness in early childhood. Developmental Medicine and Child Neurology 1993; Supplement No. 68;35(7):1–118; Miller D.L., Madge N., Diamond J., Wadsworth J., Ross E. Pertussis immunization and serious acute neurological illness in children. British Medical Journal 1993; 307:1171–1176, hereinafter ''Miller study.''). Because the Miller study looked specifically at the relationship between vaccine administration and subsequent neurological damage, the Department determined that it should not proceed with publication of the final rule until there had been a sufficient opportunity to consider the conclusions of the new Miller study. Accordingly, the Department asked the IOM to convene a Committee for purposes of evaluating the Miller study in light of the conclusions of its initial report. On March 2, 1994, the Institute of Medicine issued a report entitled ''DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis.'' On March 24, 1994, the Department published a notice in the **Federal Register** affording members of the public and additional 30 days to comment on the Miller study and the IOM report. See **Federal Register** March 24, 1994, (59 FR 13916).

The Agency also asked a subcommittee of the NVAC to review the IOM's conclusions regarding the implications of the Miller study. On March 15, the NVAC subcommittee met to review (among other things) the Miller study. The subcommittee was composed of members of the NVAC, and received input from outside experts from the fields of epidemiology, pediatric infectious disease, and pediatric neurology. The views of the NVAC are discussed below where relevant.

The ACCV reviewed the IOM report on the Miller study at its meetings in March and June, 1994. In addition, the ACCV was asked to provide comments during the additional public comment period. Comments received from two individual Commission members will be discussed below. At the June meeting, the Commission discussed in detail the Miller study and the IOM report. The consensus of the Commission was that the original table in the statute requires modification to make it consistent with current medical and scientific knowledge regarding adverse events associated with certain vaccines. The Commission was split, however, on the appropriate frame of reference for modifying the Table. Some