

suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101-239, set out as a note under section 300aa-10 of this title.

SUBPART C—ASSURING A SAFER CHILDHOOD  
VACCINATION PROGRAM IN UNITED STATES

**§ 300aa-25. Recording and reporting of information**

**(a) General rule**

Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

- (1) the date of administration of the vaccine,
- (2) the vaccine manufacturer and lot number of the vaccine,
- (3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and
- (4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

**(b) Reporting**

(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

- (A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa-14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,
- (B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and
- (C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after December 22, 1987. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of December 22, 1987.

**(c) Release of information**

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, or otherwise, to any person except—

- (A) the person who received the vaccine, or
- (B) the legal representative of such person.

(2) For purposes of paragraph (1), the term "information which may identify an individual"

shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

(July 1, 1944, ch. 373, title XXI, §2125, as added Pub. L. 99-660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100-203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330-221.)

CODIFICATION

In subsec. (b)(1), (3), "December 22, 1987" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99-660, as amended, set out as an Effective Date note under section 300aa-1 of this title.

AMENDMENTS

1987—Subsec. (b)(1), (3). Pub. L. 100-203 substituted "effective date of this subpart" for "effective date of this part".

EFFECTIVE DATE

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99-660, set out as a note under section 300aa-1 of this title.

**§ 300aa-26. Vaccine information**

**(a) General rule**

Not later than 1 year after December 22, 1987, the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

**(b) Development and revision of materials**

Such materials shall be developed or revised—

- (1) after notice to the public and 60 days of comment thereon, and
- (2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

**(c) Information requirements**

The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include—

- (1) a concise description of the benefits of the vaccine,
- (2) a concise description of the risks associated with the vaccine,
- (3) a statement of the availability of the National Vaccine Injury Compensation Program, and