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

(4) such other relevant information as may be determined by the Secretary.

(d) Health care provider duties

On and after a date determined by the Secretary which is—

(1) after the Secretary develops the information materials required by subsection (a), and

(2) not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

(July 1, 1944, ch. 373, title XXI, § 2126, as added Pub. L. 99–660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3775; amended Pub. L. 100–203, title IV, § 4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, § 6601(p), Dec. 19, 1989, 103 Stat. 2292; Pub. L. 102–531, title III, § 312(d)(15), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103–183, title VII, § 708, Dec. 14, 1993, 107 Stat. 2242.)

CODIFICATION

In subsec. (a), ''December 22, 1987'' 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

1993—Subsec. (a). Pub. L. 103–183, § 708(c), inserted ''or to any other individual'' after ''to the legal representatives of any child''.

Subsec. (b). Pub. L. 103–183, § 708(a), struck out ''by rule'' after ''revised'' in introductory provisions and substituted ''and 60'' for '', opportunity for a public hearing, and 90'' in par. (1).

Subsec. (c). Pub. L. 103–183, § 708(b), inserted in introductory provisions ''shall be based on available data and information,'' after ''such materials'', added pars. (1) to (4), and struck out former pars. (1) to (10) which read as follows:

''(1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine,

''(2) the symptoms or reactions to the vaccine which, if they occur, should be brought to the immediate attention of the health care provider,

''(3) precautionary measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur,

''(4) early warning signs or symptoms to which legal representatives should be alert as possible precursors to such major adverse reactions,

''(5) a description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authorities,

''(6) a specification of when, how, and to whom legal representatives should report any major adverse reaction,

''(7) the contraindications to (and bases for delay of) the administration of the vaccine,

''(8) an identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population,

''(9) a summary of—

''(A) relevant Federal recommendations concerning a complete schedule of childhood immunizations, and

''(B) the availability of the Program, and

''(10) such other relevant information as may be determined by the Secretary.''

Subsec. (d). Pub. L. 103–183, § 708(c), (d), in concluding provisions, inserted ''or to any other individual'' after ''to the legal representatives of any child'', substituted ''supplemented with visual presentations or oral explanations, in appropriate cases'' for ''or other written information which meets the requirements of this section'', and struck out ''or other information'' after ''Such materials''.

1992—Subsec. (b)(2). Pub. L. 102–531 substituted ''Centers for Disease Control and Prevention'' for ''Centers for Disease Control''.

1989—Subsec. (c)(9). Pub. L. 101–239 amended par. (9) generally. Prior to amendment, par. (9) read as follows: ''a summary of relevant State and Federal laws concerning the vaccine, including information on—

''(A) the number of vaccinations required for school attendance and the schedule recommended for such vaccinations, and

''(B) the availability of the Program, and''.

1987—Subsec. (a). Pub. L. 100–203 substituted ''effective date of this subpart'' for ''effective date of this part''.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate 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.

§ 300aa–27. Mandate for safer childhood vaccines

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall pre-