THE LAW

(Recording Patient Information & Reporting Adverse Events)

42 § 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 each 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 2114(b) 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 the effective date of this part [Effective 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 the effective date of this part [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, United States Code, 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 persons 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, 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.