

42 USC 300aa-25: Recording and reporting of information

Text contains those laws in effect on December 24, 2018

From Title 42-THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A-PUBLIC HEALTH SERVICE

SUBCHAPTER XIX-VACCINES

Part 2-National Vaccine Injury Compensation Program

subpart c-assuring a safer childhood vaccination program in united states

Jump To:

[Source Credit](#)

[Codification](#)

[Amendments](#)

[Effective Date](#)

§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.