

42 USC 300aa-28: Manufacturer recordkeeping and reporting

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

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§300aa–28. Manufacturer recordkeeping and reporting**(a) General rule**

Each vaccine manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any State, shall, with respect to each batch, lot, or other quantity manufactured or licensed after December 22, 1987-

(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity,

(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer's representative) conducted, including the date of the test, the type of vaccine tested, the identity of the batch, lot, or other quantity tested, whether the batch, lot, or other quantity tested is the product of repooling or reworking of previous batches, lots, or other quantities (and, if so, the identity of the previous batches, lots, or other quantities which were repooled or reworked), the complete test results, and the name and address of the person responsible for conducting the test,

(3) include with each such report a certification signed by a responsible corporate official that such report is true and complete, and

(4) prepare, maintain, and upon request submit to the Secretary product distribution records for each such vaccine by batch, lot, or other quantity number.

(b) Sanction

Any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required under paragraph (1) or (2) of subsection (a) shall-

(1) be subject to a civil penalty of up to \$100,000 per occurrence, or

(2) be fined \$50,000 or imprisoned for not more than 1 year, or both.

Such penalty shall apply to the person who intentionally destroyed, altered, falsified, or concealed such record or report, to the person who directed that such record or report be destroyed, altered, falsified, or concealed, and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment shall be treated as a separate occurrence.

(July 1, 1944, ch. 373, title XXI, §2128, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3777 ; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221 .)

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

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